QUALITY MANAGEMENT PLAN

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ARIZONA DEPARTMENT OF ENVIRONMENTAL QUALITY
QUALITY MANAGEMENT PLAN

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EXECUTIVE SUMMARY

The Arizona Department of Environmental Quality (ADEQ) Quality Management Plan (QMP), prepared in accordance with the requirements of the U.S. Environmental Protection Agency (EPA) Order 5360.1, defines the ADEQ Quality Management System. The QMP describes specific quality management practices employed by the Agency for the following types of data generation and monitoring activities:

1. Data generated by field sampling and laboratory analysis;
2. Data generated and used for design, construction and operation of engineered remediation/treatment systems; and,
3. Data acquired from sources outside ADEQ through databases, publications, etc.

The primary goal of the ADEQ Quality Management System is to ensure that all of the agency environmental programs produce results that are of known quality, and that the results are of the type and quality needed and expected for their intended uses. Because environmental data collected by the ADEQ are frequently used for regulatory decision making, that data must be appropriately documented, and scientifically and legally defensible.

The ADEQ organization and management principles, as identified in this document, rely on staff empowerment and the encouragement of "quality" performance to attain the goals of this QMP. The ADEQ has empowered its Quality Assurance/Quality Control (QA/QC) Unit to assist in QA assessment and response activities. The ADEQ QA/QC Unit is ultimately responsible for oversight of the ADEQ' s Quality Management System, and for preparation and presentation of specialized training to staff within the Agency programs. The QMP specifies the general and program-specific quality systems required by EPA Region IX to implement the principles outlined in the previous paragraphs.

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CHAPTER 1
ORGANIZATION AND MANAGEMENT

1.1 QUALITY ASSURANCE (QA) POLICY

1.1.1 Document Purpose

The Quality Management Plan (QMP) describes the quality management processes the Arizona Department of Environmental Quality (ADEQ) uses to maintain a Quality Management System consistent with the U.S. Environmental Protection Agency (EPA) requirements. The QMP was prepared in accordance with the August 1996 edition of the internal EPA requirements document numbered EPA QA/R-2, and entitled ***"Requirements for Quality Management Plans,"*** and to comply with EPA Order 5360.1, entitled ***"Policy and Program Requirements for the Mandatory EPA Quality System."***

1.1.2 Definition of Quality Assurance/Quality Control (QA/QC)

Quality Assurance (QA) is an integrated system of management activities involving planning, implementation, assessment, reporting and quality improvement to ensure that a process, item, or service is of the type and quality needed and expected by the customer.

Quality Control (QC) is the overall system of technical activities that measures the attributes and performance of a process, item or service against defined standards to verify that they meet the stated requirements established by the customer. The QC system includes operational techniques and activities that are used to fulfill requirements for quality.

At the ADEQ, the Quality Management System is implemented largely through the following Agency functions:

1. Mandated QA/QC training for certain identified job functions (with ADEQ QA/QC assistance);
2. Mandated use of Agency QA Program Plans (QAPrPs);
3. Mandated use of Agency QA Project Plans (QAPjPs);
4. Clearly defined ADEQ QA/QC Unit oversight responsibilities;
5. Periodic Management Systems Reviews (MSRs) and Technical System Audits (TSAs) performed by the ADEQ QA/QC Unit; and,
6. A QA forum to focus continuous improvement efforts.

Each of these systems is discussed in more detail in the appropriate location within this document. The document officially establishes these requirements as components of the ADEQ Quality Management System.

Quality Control (QC) is largely implemented on a project by project basis through the mandated use of Quality Assurance Project Plans (QAPjPs) and required data assessment

activities. Designated Agency Project Managers, through a review and approval process involving the ADEQ QA/QC Unit, are individually responsible for assuring that the QAPjP is capable of producing reliable work, of known quality, which meets stated project needs.

1.1.3 Importance of QA/QC to the ADEQ

Managers and staff at the Arizona Department of Environmental Quality (ADEQ) make daily decisions which affect the lives and livelihoods of millions of people who reside within the State. The quality of air, land and water as they affect public health and the environment is the focus of our mission. The quality of decisions made by the ADEQ depends heavily on the quality of information used to make those decisions. While other factors such as the law, public opinion, and Court direction also influence our judgment, nothing is more fundamental to our daily decisions than environmental data. If those data are not of adequate quality to support its intended use, then subsequent decisions will suffer commensurately.

Environmental data are used for setting priorities; strategic direction; targeting inspections; measuring compliance; identifying enforcement actions; measuring progress and trends; certifying laboratories and for many other uses. Environmental data are frequently critical because they can impact our programs' direction and emphasis, determine whether an enforcement case can be successful, or dictate which of several cleanup options will be implemented at a contaminated waste site.

The consequences of "poor" data (that which does not meet the user requirements) are that our individual and collective decisions are not as sound as they could or should be. However, the effects of data can be of extreme significance, such as when an enforcement case has to be withdrawn because our own underlying compliance data are successfully challenged by defendants.

The ADEQ is involved in conducting studies that have goals in four broad categories:

Identifying the presence of environmental contaminants in areas of potential exposure to humans or the environment;
Determining the impacts of environmental contaminants on human health and ecosystems;
Determining whether, how, and by whom such threats to human health and the environment should be remediated; and,
Monitoring compliance with environmental regulations.

QA/QC is integral to the functions of this State Agency because quality data ensure the scientific credibility of the data on which decisions are based. Proper QA enhances proper planning, reducing the likelihood of duplicative and repetitive sampling, thereby reducing costs to the taxpayers.

1.1.4 General Goals and Objectives of the ADEQ

The ADEQ' s Quality Management System is designed to avoid occasions where the environmental data collected fall short of meeting the data quality objectives (DQOs) established by the users of the data. The primary goal of the ADEQ Quality Management System is to ensure that all environmentally related data collection and processing activities performed by or under the Agency' s oversight will result in the production of data that are both documented and of known quality, and can be used with a high degree of certainty by the intended user to support specific decisions or actions. The ADEQ Quality Management System applies to those monitoring and measurement activities supported by EPA through grants, contracts or interagency agreements. The ADEQ Quality Management System will be achieved by ensuring that appropriate resources are made available and that the proper procedures are followed throughout the entire process of planning, collecting, analyzing and interpreting environmental data.

The goals of the ADEQ QA System are to:

Encourage the use of QA/QC principles in the management of environmental projects;
Facilitate the timely identification of problems and implement corrective actions,
Identify training needs;
Identify and correct systemic weaknesses; and,
Provide for continuous improvement in Agency operations.

The primary management principles that the ADEQ uses in its QA System are:

Empowerment of staff, and
Encouragement of good performance.

Specifically, it is ADEQ' s policy that:

1. All programs generating, using, or requiring the collection of environmental data will follow the requirements outlined in this Quality Management Plan (QMP) and subsequent ADEQ policies and Standard Operating Procedures (SOPs).

2. The objectives for generating any new environmental data will be determined ***prior to*** data collection activities so that appropriate resources, and QA/QC control methods can be applied to ensure a level of data quality commensurate with the intended use(s) for the data.

3. A comprehensive QAPrP will be used to detail activities under the regulatory program. Each program or activity that generates environmental data will develop and implement a QA Program Plan (QAPrP) and/or a QA Project Plan (QAPjP) containing SOPs which specify the detailed procedures required to assure production of quality data. The QAPrPs shall be prepared by the Divisions, under the direction of the ADEQ QA/QC Unit, in conjunction with the technical programs. Effective organizational QAPjPs and SOPs shall be developed and implemented as required

and will be approved as shown in number 5 below.

4. All new environmental data generated by the Agency will be of known and documented quality, as defined by pre-established data quality objectives (DQOs). The process of defining DQOs should be accomplished using a systematic planning process. The DQO planning process should be consistent with EPA' s ***"Guidance for the Data Quality Objective Process,"*** EPA QA/G-4, September 1994, or an equivalent document.

5. The ADEQ QA/QC Unit will be the focal point for interaction between EPA' s Regional IX QA Office and the ADEQ. Technical authority for QA matters will be assigned to the ADEQ QA/QC Unit.

   The QAPjPs developed for sites funded by EPA monies shall be prepared by the originating ADEQ program and reviewed and approved by either EPA or the ADEQ QA/QC Unit prior to the start of any data collection effort. If the ADEQ QA/QC Unit lacks the resources to provide a timely review of a QAPjP, then the originating program has the option to utilize the services of a private contractor or an independent reviewer from another program within the Division. This option is contingent upon EPA' s prior written approval.

   A separate stand alone QAPjP will be developed, as appropriate, for site-specific projects undertaken by the organization utilizing non-EPA resources and shall be reviewed by the ADEQ QA/QC Unit. QAPjPs developed for sites independent of EPA monies shall be submitted initially to the ADEQ QA/QC Unit for review and approval. If the ADEQ QA/QC Unit lacks the resources to provide a timely review, then the originating program has the option to either utilize the services of a qualified contractor or other independent ADEQ staff as deemed appropriate. Short-term projects and one-time events (e.g. emergency response) do not require QAPjPs as the sampling protocols and objectives are addressed in the program' s QAPrP.

6. Regular technical systems audits (TSAs) will be conducted by the ADEQ QA/QC Unit on contractors and ADEQ projects involving environmental data collection to ensure that they comply with the ADEQ Quality Management System requirements. The TSA is a process used to measure the conformance of a measurement system to the criteria defined by the ADEQ. Additionally, the ADEQ Quality Management System **may** involve periodic management systems reviews (MSRs). Deficiencies highlighted in these assessments will be addressed in a timely manner.

7. The requirements of the QMP may be waived only under exceptional circumstances. Each waiver will be considered by the ADEQ QA/QC Unit on its own merits upon receipt of a written request from the program. The waiver must also be approved by the EPA Region IX Quality Assurance Manager. The waiver request will be addressed to the ADEQ QA/QC Unit and must address the requirement to be waived, the rationale and the consequences of non-approval. When a waiver is

granted, the actual procedures for the data management activities will be documented and available for review and assessment during the decision-making associated with the project.

1.1.5 Resources for the QA System

The resources necessary to conduct the various QA and QC activities within the ADEQ are provided by the ADEQ Management and, in some cases, by the program staff who require assistance in order to successfully implement their programs. QA is viewed as an integral part of the programs and activities to which QA applies (i.e., any program which deals with environmental measurements and data generation). This includes all monitoring activities. The level of QA resources needed for any given program or project is determined initially by the relevant program or project manager based upon experience with similar QA efforts.

The ADEQ provides in-house and contracted expertise in quality assurance and technical support in several scientific disciplines to all programs within the Agency. These support services include data quality assessments, data validation and evaluation provided by chemists, toxicologists, engineers and others. Personnel to provide these services are located either in the ADEQ itself, or within other State Agencies such as the Arizona Department of Health Services (ADHS).

1.2 SCOPE OF THE QUALITY MANAGEMENT PLAN

The ADEQ QMP is intended to establish the foundation for implementing an effective QA program within ADEQ and cover at a minimum internal and external activities which involve the generation of environmental data for programs funded by EPA.

At a minimum, the QMP applies to ADEQ programs, activities, grants, contracts and interagency agreements that generate environmental data which is used to make decisions or support actions related to the Agency' s defined mission and responsibilities funded by EPA. Environmental data are defined as information or measurements resulting from field data collection activity, laboratory analyses or models involving the assessment of chemical, physical or biological factors relating to the environment. Therefore, any programs, activities, etc. which generate such data are required to comply with the requirements of this QMP.

1.2.1 Types of Activities Specifically Covered by the ADEQ QMP

There are three types of data generation and monitoring activities covered under this QMP. The three categories are as follows:

1. Data generated by field sampling and laboratory analysis;
2. Data generated and used for design, construction and operation of engineered remediation/treatment systems; and
3. Data acquired from sources outside ADEQ through databases, publications, etc. (ex. data quality indicators are identified and evaluated).

Activities that fall under one of these three categories must be implemented in accordance with the QA requirements of EPA Order 5360.1. Health and Safety monitoring data are specifically not included and is not subject to the requirements herein.

Whenever these activities are performed directly by the ADEQ or State contractors under the State' s supervision, the ADEQ Project Manager, with support from the ADEQ QA Unit, has full responsibility for ensuring that all ADEQ QA requirements are met. When such activities are performed with EPA funds through an external funding mechanism such as Inter-Agency Government Agreements, Grants or Program funds given to the State, the ADEQ Project Manager, with support from the ADEQ QA Unit, is responsible for ensuring that the State complies with all relevant EPA QA requirements.

Since ADEQ employs a primarily decentralized approach to quality management, each ADEQ Division is responsible for determining the specific environmental programs and activities to which the ADEQ Quality Management System will apply. However, the following is a sampling of the types of environmental programs, grants and activities within each of the Divisions which may be covered by the ADEQ Quality Management System.

AIR QUALITY DIVISION:

Air Assessment Section
- Monitoring Unit
- Special Projects Unit
- Evaluation Unit

Permits Section
- New Source Unit
- Existing Source & General Permit Unit

Compliance Section
- Inspections & Field Services Unit
- Technical Services Unit

WASTE PROGRAMS DIVISION:

Waste Programs Capacity Development Section
- Voluntary Sites Unit

Superfund Programs Section
- Site Assessment Unit
- Remedial Projects Unit
- Federal Projects Unit
- Remedial Investigations Hydrology Unit

Hazardous Waste Section
- Hazardous Waste Inspections and Compliance Unit
- Emergency Response Unit

Underground Storage Tank (UST) and Program Support Section
- UST Inspections & Compliance Unit

Underground Storage Tank Corrective Action Section
- State Lead Unit
- Site Investigations and Remediation Units

Enforcement Unit
Technical Support Unit
Claims Review Unit

Solid Waste Section
Inspections & Compliance Unit

WATER QUALITY DIVISION:

Water Permits Section
Municipal Wastewater and Recharge Unit
Industrial and Storm Water Unit
Mining Unit
Domestic Wastewater Unit
Reuse and Federal Permits Unit

Water Quality Compliance Section
Drinking Water Compliance, Tracking & Enforcement Unit
Water Quality Enforcement Unit
Water Quality Data Unit

Hydrologic Support & Assessment Section
TMDL and Assessment Unit
Groundwater Monitoring Unit
Surface Water Monitoring and Standards Unit

Drinking Water Section
Monitoring/Assessment Unit
Technical Engineering Unit

Water Quality Planning Section
Watershed Unit

Data Management & Analysis Group

NORTHERN REGIONAL OFFICE:

Field Services East
Field Services West

SOUTHERN REGIONAL OFFICE:

Field Service Group
Border Programs Unit
Superfund Program Unit
Water Systems Unit

1.2.2 Data Generated by Field Sampling and Laboratory Analysis

Some examples of activities covered under the ADEQ QMP are the generation of environmental data, including field work for the purposes of collecting samples for chemical, physical or biological analyses; the collection of in situ measurements; field work for site characterization and remediation; and, compliance inspections.

Environmental media samples for chemical, physical or biological analyses are commonly

collected by, or for, the ADEQ and analyzed to accomplish the following goals:

Confirmation of the presence or absence of pollutants or contaminants;
Determination of contaminant concentration levels of various sample components;
Determination of the sources of contamination;
Delineation of the horizontal and vertical distribution;
Evaluation of the rate and direction of transport;
Determination of the eventual fate of the identified pollutants;
Determination of the effectiveness of treatment; and,
Establishment of time trends, monitor changes, evaluate progress, and to evaluate compliance with environmental laws and regulations.

The above sampling activities may be conducted for site characterization, for ongoing monitoring programs, or during remediation and removal activities. Any data collected for the State may also be potentially used as an input for risk screening and/or assessment calculations incorporating exposure to humans, wildlife and the environment.

Data collection activities conducted for the ADEQ must be adequately addressed in a Quality Assurance Project Plan (QAPjP), which most likely will include a project specific Sampling and Analysis Plan (SAP).

Activities covered under this category include collecting media samples in the field, observing and recording field observations, performing analyses in the field and in field (mobile) laboratories, and analyzing samples in fixed laboratory settings. Examples of media include solid or liquid waste, fluid discharges or emissions, groundwater, surface water, soil, sediment, air, and biota. Measurements include physical measurements and observations made in the field such as flow rates, water levels, particle sizes, geological matrices, etc. Biological monitoring and sampling activities such as habitat evaluation, species identification and diversity assessments are also covered under this category. Portable equipment can be used to make field chemical determinations of such parameters as pH, temperature and specific conductance. The QAPjPs shall describe methods of collection, methods of analyses, methods of transportation, and methods of documentation for each of these activities.

1.2.3 Technical Activities Not Covered by the ADEQ QMP

Two types of data collection activities that are generally not covered by the QMP are indicated and clarified below:

1. Data collected only for safety or workplace regulations are not covered in the QMP. However, if the same data are used to identify hot spots for subsequent investigation, the collection is covered by the QMP.

2. Collection of employee medical monitoring data are generally not covered under the QMP. However, if that data are used to determine risk factors related to work exposure, it would generally be covered.

1.3 ADEQ ORGANIZATIONAL STRUCTURE

The ADEQ employs a decentralized approach to QA management, whereby each Division and Regional Office is responsible for deciding how they will specifically implement the general policies and procedures of this QMP. The ADEQ Director has delegated day-to-day responsibility for overseeing the Quality Management System to the ADEQ QA/QC Unit.

The Leadership Team is that group of ADEQ Management assembled and under the direction of the ADEQ Director. The Leadership Team consists of the following members: ADEQ Director; Deputy Director; Waste, Water, Air and Administrative Directors; Northern and Southern Regional Managers; Communications Officer; ADEQ Administrative Council and the Manager of General and Laboratory Services.

Currently, the ADEQ QA/QC Unit is managed by a QA/QC Program Supervisor and staffed with two QA Program Specialists and a half-time Administrative Assistant. The QA/QC Program Supervisor has direct access and reporting authority to the General and Laboratory Services Section Manager. The General and Laboratory Services Manager has direct access and reporting authority to the ADEQ Director. The QA/QC Unit maintains an independence in both location and function from any offices or programs which generate environmental data.

The ADEQ is composed of three major program Divisions (Air, Waste and Water) that generate environmental data as well as an Administration Division. The ADEQ QA/QC Unit provides support to each of the three ADEQ Divisions that generate environmental data and functions as the Agency technical QA expert and assists with a variety of QA functions.

1.4 ROLES AND RESPONSIBILITIES

Anyone in the ADEQ who is either directly or indirectly involved with environmental data collection or laboratory analyses has some responsibility for ensuring data quality. This may include staff level personnel, program supervisors, unit managers, section managers, deputy division directors, division directors, the deputy director and the ADEQ Director. The following is an overview of the QA responsibilities of *some* of the ADEQ Agency personnel:

1.4.1 ADEQ QA/QC Program Supervisor Authority

The ADEQ QA/QC Program Supervisor has the authority and responsibility for managing the QA activities within the ADEQ Quality Management System. The ADEQ QA/QC Unit may recommend suspension of environmental data collection projects and request corrective action in the event that data quality/environmental technology QA activities do not meet the Agency QA policy or requirements. If the ADEQ QA/QC Program Supervisor and Project Manager are unable to resolve the QA issues at the staff level, those concerns shall be elevated to the appropriate ADEQ upper-management. There shall be a seven day period in which management must respond in writing to the ADEQ QA/QC Unit informing the QA/QC Unit of the program' s

final decision.

The ADEQ QA/QC Unit is specifically responsible for ensuring that:

All internal and external projects involving the generation of environmental data are performed in accordance with the ADEQ QMP and an approved QAPjP;

Adequate procedures required to implement QA management requirements are identified and provided;

Laboratory audits are performed and analytical data are validated as necessary;

Formal reviews and assessments of QA and QC activities are conducted and reports on such assessments are prepared and forwarded to Section Managers. The ADEQ QA/QC Unit will make recommendations for appropriate corrective action as indicated by audit findings;

Technical assistance to ADEQ programs and contractors is provided and EPA guidance documents, policies and procedures are distributed as appropriate; ADEQ training needs are assessed. The ADEQ QA/QC Unit shall arrange, develop and/or present training courses on QA topics; and,

An adequate degree of auditing by the ADEQ QA/QC Unit [i.e., management system reviews (MSR) and technical system audits (TSAs)] is performed to assess compliance with the ADEQ QA requirements for monitoring and evaluating overall project implementation.

The QAPjPs specifically address the technical adequacy of DQOs.

1.4.2 Line Management and Staff Authority

1.4.2.1 ADEQ Director:

The ADEQ Director has overall responsibility for the ADEQ QA Program as outlined in EPA Order 5360.1. More specifically, the ADEQ Director is responsible for ensuring that QA is an identifiable activity having adequate resources allocated for the accomplishment of the mission goals for the ADEQ centralized programs as well as its satellite (Northern and Southern) regional offices. These goals include providing the resources for the collection of the right type, quantity and quality of data for all in-house and external projects.

1.4.2.2 ADEQ Division Directors:

The Division Directors have the overall responsibility for managing the QA Program within their organization in accordance with the ADEQ QMP. The Directors are specifically responsible for ensuring that adequate resources are provided to support the ADEQ

QA program responsibilities.

1.4.2.3 ADEQ Section Managers:

Section Managers must ensure that:

To the extent required, a Project Manager is designated to coordinate and assist the ADEQ QA/QC Unit to ensure implementation of the ADEQ Quality Management System when environmental measurements are to occur. This coordination may also occur through the designated program staff with the QA/QC Unit.

All ADEQ environmental data collection activities involve appropriate planning and documentation regarding data quality objectives (DQOs), quality assurance program plans (QAPrPs), and standard operating procedures (SOPs);

ADEQ site-specific QAPjPs are written by program personnel, contractors or responsible parties and are approved by the ADEQ QA/QC Unit, or by the ADEQ program if authorized by EPA, to ensure effective implementation for all those projects which generate environmental data;

Deficiencies identified in audits are corrected expeditiously; and,

Program-specific QA-related training needs are identified.

Section Managers may delegate some or all of these tasks to Unit Managers.

1.4.2.4 ADEQ Project Managers:

Project Managers may be assigned the responsibility for specific projects supported through contracts, grants or interagency agreements (IGSs). The ADEQ QA requirements shall be followed for those internal activities and external oversight projects which generate environmentally related data. In addition to the ADEQ QMP, the relevant QA requirements for external projects are specified in 40 CFR 30 and 31, and 40 CFR 15. The ADEQ Project Manager has the principal responsibility for ensuring that the project data quality objectives are met. Paramount among those requirements are that an approved Quality Assurance Project Plan (QAPjP) is established prior to initiating any data collection efforts.

ADEQ Project Managers must ensure:

That at a minimum, all EPA funded projects performed either internally or through external contracts must be brought to the attention of the ADEQ QA/QC Unit and that QAPjPs are approved prior to data environmental collection activities as specified in section 1.1.4.5;

That Data Quality Objectives (DQOs), specification, and acceptance criteria for the projects have been prepared by the program and approved prior to data collection activities as specified in section 1.1.4.5;

Their availability to participate in conducting QA system/performance audits of projects as necessary with the ADEQ QA/QC Unit;

That appropriate corrective action is taken if indicated in the audit findings; and,
That unresolved data quality problems are reported to the ADEQ QA/QC Unit and designated program staff.

1.5 COMMUNICATIONS

To be effectively implemented, the QMP must not only be approved, circulated and regularly updated, but understood by those responsible for its implementation. Two means will be used to ensure that this occurs. The ADEQ QA/QC Program Supervisor will keep Division and Agency Management apprised of QA issues as new information, policies, or other QA procedures develop. The ADEQ QA/QC Unit will also provide training on an on-going basis in order to ensure that personnel responsible for QA functions understand QA requirements and practices related to their responsibilities.

CHAPTER 2 QUALITY MANAGEMENT SYSTEM

2.1 PRINCIPAL COMPONENTS OF THE QUALITY MANAGEMENT SYSTEM

The Quality Management System consists of staff, defined functions, tools and quality assurance (QA) procedures which are used to ensure that appropriate quality of environmental data are generated for the needs of ADEQ users and decision makers. The ADEQ QA/QC Unit has suggested the following twelve essential elements which comprise an effective QA System:

1. A statement of the ADEQ QA Goals and Policy (identified in the ADEQ QMP);

2. Adhering to applicable ADEQ QA requirements and criteria (EPA Orders, regulations and guidelines);

3. Defining the ADEQ QA organizational structure;

4. Describing ADEQ programs and activities covered by the QA requirements;

5. Outlining the roles and responsibilities of those involved with ADEQ QA functions;

6. Utilizing QA tools and procedures;

7. Identifying resource allocations;

8. Establishing a communications process (internal and external);

9. Affording QA training opportunities;

10. Dictating documentation and record keeping requirements;

11. Implementing review and evaluation procedures to ensure continuous improvement; and,

12. Defining of key QA terminology.

2.2 PRINCIPAL TOOLS OF THE QUALITY MANAGEMENT SYSTEM

The successful implementation of the ADEQ Quality Management Program requires a consistent and graded approach for QA practices commensurate with the intended uses of the data and degree of confidence needed in the results. The ADEQ QMP requires that a variety of tools and procedures be utilized for planning, implementing and evaluating the Quality Management System. ADEQ Managers and staff members will be informed of the availability and use of these tools through the ADEQ QA/QC Unit training.

The primary QA planning and implementation tools include a Quality Management Plan (QMP), establishment of Data Quality Objectives (DQOs), Quality Assurance Program Plans (QAPrPs), Quality Assurance Project Plans (QAPjPs), Standard Operating Procedures (SOPs) and Sampling and Assessment Plans (SAPs) or Field Sampling Plans (FSPs). Most of these tools are currently employed directly by the ADEQ program staff, with technical assistance as necessary from the ADEQ QA/QC Unit.

The primary QA evaluation and assessment tools comprising the ADEQ Quality Management System include Management System Reviews (MSRs), Technical System Audits (TSAs), Performance Evaluation (PE) Studies, and Data Quality Assessments (DQAs). Most of these are either arranged and/or performed by the ADEQ QA/QC Unit.

All environmental data collection activities conducted by, or on behalf of EPA Region IX, must be addressed in a Quality Assurance Project Plan (QAPjP). All QAPjP' s must be developed as specified in EPA QA/R-5, ***EPA Requirements for Quality Assurance Project Plans for Environmental Data Operations.*** The ADEQ requires that all twenty-four elements be addressed appropriately before the ADEQ QA/QC Unit may approve a QAPjP. These elements consist of the following:

Group A: **Project Management**

- A1 Title and Approval Sheet
- A2 Table of Contents
- A3 Distribution List
- A4 Project/Task Organization
- A5 Problem Definition/Background
- A6 Project/Task Description
- A7 Quality Objectives and Criteria for Measurement Data
- A8 Special Training Requirements/Certification
- A9 Documentation and Records

Group B **Measurement/Data Acquisition**

- B1 Sampling Process Design
- B2 Sampling Methods Requirements
- B3 Sample Handling and Custody Requirements
- B4 Analytical Methods Requirements
- B5 Quality Control Requirements

B6 Instrument/Equipment Testing, Inspection, and Maintenance Requirements
B7 Instrument Calibration and Frequency
B8 Inspection/Acceptance Requirements for Supplies and Consumables
B9 Data Acquisition Requirements
B10 Data Management

Group C **Assessment/Oversight**

C1 Assessments and Response Actions
C2 Reports to Management

Group D **Data Validation and Usability**

D1 Data Review, Validation and Verification Requirements
D2 Validation and Verification Requirements
D3 Reconciliation with User Requirements

These elements explicitly require the development of Data Quality Objectives (DQOs) for each planned data collection activity and also require that data assessments be conducted to evaluate the validity of the results.

Every field investigation should be constructed in accordance with an approved ADEQ QAPjP to ensure that DQOs will be met. ADHS State statutes require that all laboratories generating analytical data for submission to the ADEQ for regulatory purposes must be licensed by the ADHS Office of Laboratory Licensure.

2.2.1 Quality Management Plan (QMP)

The ADEQ QMP describes the policies, procedures and systems governing Agency data collection activities. It serves as the "umbrella" document for all QA operations. Future revisions and updates to this QMP will be prepared by the ADEQ QA/QC Program Supervisor. The proposed revisions will be submitted to the ADEQ Leadership Team for comment within 10 working days. The ADEQ QA/QC Program Supervisor will forward the revised QMP, and applicable comments, to the Director for adoption within 15 working days.

2.2.2 Data Quality Objectives Process (DQO)

The ADEQ is committed to sound science and thus, the generation of environmental data that are technically and legally defensible, and of adequate quality and quantity to support regulatory decisions. The Data Quality Objectives (DQO) process is used in the planning phase of all Agency data collection activities. The "***Guidance for the Data Quality Objectives Process***," EPA QA/G-4 is used, as appropriate, for the development of DQOs by the Agency. DQOs are a required element of any Quality Assurance Project Plan (QAPjP) submitted to the ADEQ QA/QC Unit for review and approval. This requirement is applicable to all parties that generate environmental data for use by the ADEQ.

Each program within the ADEQ is responsible for establishing DQOs for projects where ADEQ takes the lead role in gathering environmental data or for those projects where ADEQ provides oversight. The ADEQ QA/QC Unit will provide technical assistance as warranted in determining the appropriateness of the DQO process relative to the intended use of the data.

The development of data quality objectives (DQOs) is outlined in QA/R-5. For many projects, DQOs may be a simple statement of why data are being collected and what data outputs will be considered significant. For other projects, the complete statistical hypothesis testing approach as described in Agency Guidance QA/G-4, "***Guidance for the Data Quality Objectives Process***," may be appropriate. The ADEQ QA/QC Unit must assure that the QAPjP specifically addresses the technical adequacy of DQOs. Compliance with QA/G-4 is highly recommended but is not mandatory.

Data Quality Objectives are intended to accomplish the following

Clarify the project objectives;
Define the most appropriate types of data to collect;
Determine the most appropriate conditions under which to collect the data; and,
Specify the level of uncertainty that is acceptable as the basis for establishing the quantity and quality of data needed.

2.2.3 Quality Assurance Project Plans (QAPjP)

The QAPjP dictates the policies and procedures; project organization and objectives; and, QA requirements and quality control activities designed to achieve the desired type and quality of environmental data necessary to support the project objectives. In the ADEQ, for regulatory purposes, and those activities funded by EPA, no collection or analyses for long-term or large scale projects will occur without the approval of a supporting QAPjP. Short-term projects and one-time events (e.g. emergency response) do not require QAPjPs as the sampling protocols and objectives are addressed in the program' s QAPrP. Additionally, all contractors for the ADEQ must meet the quality assurance and program requirements established by the ADEQ QMP.

2.2.4 Quality Assurance (QA) Status Reports

Each QAPjP for environmental data collection must include a section discussing the frequency, content, and format of the required QA status report(s). These factors will be determined by the relevant ADEQ Program Project Manager or designated program staff and the ADEQ QA/QC Unit. Any status reports will be submitted by the ADEQ Project Manager to the ADEQ QA/QC Unit and will be used to help track the project' s progress. Each status report must address, as a minimum, the following elements:

Status of the project;
Changes that occurred in project activities (sampling, QC control measures, analytical methods);
Results of performance and system audits as they apply;

Any corrective actions taken;
Any project organizational changes; and,
Results of the assessment of data quality indicators (precision, accuracy, completeness, representativeness and comparability).

2.2.5 Standard Operating Procedures (SOP)

The use of standard operating procedures (SOPs) in the ADEQ serves as one mechanism to ensure comparability across programs and individual environmental data collection projects. SOPs must be incorporated either in full or by reference in the QAPjPs. SOPs developed by the ADEQ must be peer reviewed and receive approval by the ADEQ QA/QC Unit as appropriate.

2.2.6 Technical Systems Audit (TSA)

All ADEQ programs that employ environmental sample collection and analyses are subject to a TSA. The TSA involves a thorough review of the field equipment; sampling and analyses procedures; documentation; data validation; and, training procedures for collecting or processing environmental data. TSAs may be routinely planned by the ADEQ QA/QC Unit, specifically requested by the ADEQ Project Manager, or result from the findings of another audit or review. The ADEQ QA/QC Unit Program Supervisor is responsible for assembling the audit team. Results will be reported to the audited organization in the form of a written report within 14 calendar days of the completion of the audit or a mutually agreed upon alternative. Written comments by the ADEQ Project Manager must be supplied to the ADEQ QA/QC Unit within 14 calendar days of receipt of the audit findings or a mutually agreed upon alternative. Copies of the TSA Audit Final Report will be stored in the project file and also with the ADEQ QA/QC Unit. Additional copies will be distributed as appropriate.

2.2.7 Management System Reviews (MSR)

Management System Reviews (MSRs) will be performed periodically within the ADEQ for all programs. The MSR will qualitatively assess a program' s data collection procedures to determine if the ADEQ Quality Management System is adequate to ensure the quality of the program' s data. The ADEQ QA/QC Program Supervisor is responsible for assembling the audit team and coordination of the audit activities.

Guidance for performing MSRs is contained in EPA Guidance Document QA/G-3. All MSRs will result in the production of a written report. A draft of this report is due within 30 days of the completion of the observation phase of the audit. The draft will be sent for comments to the program' s senior management. Comments must be supplied by the program' s senior management within 30 days of the receipt of the draft. Final reports are to be completed within 30 days of receipt of comments by the program' s senior management

2.3 OPTIONAL PRACTICES FOR THE CONTROL OF DATA COLLECTION

ACTIVITIES

2.3.1 Field Audits

These are "real-time" observation, review and critical appraisal of field sampling activities. Field audits consist of an on-site visit to the sampling location; observation of sampling practices; review of project records and sampling SOPs; and, documentation of findings. The primary intention of such audits is to ascertain whether QAPjP specified practices are being followed.

When sampling is being performed by ADEQ personnel or ADEQ contractors, the lead auditor must be an ADEQ employee. In these circumstances, audits may be requested through the ADEQ QA/QC Unit, and are performed by non-project personnel to avoid the appearance of bias.

All field auditing activities will result in the production of a written report. A draft of this report is due within 7 days of the completion of the observation phase of the audit. The drafts will be sent for comments to the ADEQ Project Manager responsible for the activity observed prior to completion of the report. Written comments by the ADEQ Project Manager must be supplied to the ADEQ QA/QC Unit within 7 days of the receipt of the draft. Final reports generated by the ADEQ QA/QC Unit are to be completed within 30 days of receipt of comments from the ADEQ Project Manager. Copies of the Final Report will be stored in the Project file and also with the ADEQ QA/QC Unit. Additional copies will be distributed as appropriate.

2.3.2 Laboratory Audits

These are audits of laboratory operations. Such audits may be "real-time" (i.e. performed while project samples are under analysis, or performed after analysis is completed). Laboratory audits will consist of an on-site visit to the laboratory; observation of analytical practices when possible; review of project records and laboratory SOPs; and, documentation of findings. A laboratory audit is conducted to determine and document whether laboratory practices and analytical procedures used are consistent with QAPjP requirements and laboratory tasking instructions.

When analyses are being performed by ADEQ contractors, the lead auditor must be an ADEQ employee. In these circumstances, audits may be requested through the ADEQ QA/QC Unit, and are performed by non-project personnel to avoid the appearance of bias.

All laboratory auditing activities will result in the production of a written report. A draft of this report is due within 7 calendar days of the completion of the observation phase of the audit or a mutually agreed upon alternative. The draft will be sent for comments to the ADEQ Project Manager responsible for the activity observed prior to completion of the report. Written comments must be supplied by the ADEQ Project Manager to the ADEQ QA/QC Unit within 7 calendar days of the receipt of the draft or a mutually agreed upon alternative. Final reports generated by the ADEQ QA/QC Unit are to be completed within 30 calendar days of receipt of comments by the ADEQ Project Manager or a mutually agreed upon alternative. Copies of the

Final Report will be stored in the Projects file and also with the ADEQ QA/QC Unit. Additional copies will be distributed as appropriate.

CHAPTER 3 PERSONNEL QUALIFICATIONS AND TRAINING

3.1 POLICY FOR QUALITY ASSURANCE (QA) RELATED TRAINING

The purpose of this Chapter is to explain the processes used by ADEQ to ensure that staff and managers working in various environmental programs are trained and qualified to perform their required QA responsibilities. This includes project managers, field personnel, ADEQ QA/QC staff, data processors and the individuals who supervise these personnel.

3.1.1 Responsibilities

The ADEQ Program Unit Managers are responsible for ensuring that each staff member involved with collecting or analyzing environmental data has the necessary technical, quality assurance and project management training required for their assigned tasks and functions. Section Managers are also responsible for ensuring that technical staff maintain the necessary level of proficiency to effectively meet the ADEQ QA responsibilities. The ADEQ QA/QC Unit will provide QA training on a semi-annual basis to update program staff with developing QA issues.

Maintaining staff proficiency in critical technical disciplines (e.g., environmental engineers, geologists, hydrologists, hydrogeologists, chemists and microbiologists) is the joint responsibility of the individuals filling those positions and the program manager and/or supervisor.

3.1.2 Identification of Training Needs

Generally, QA-related training needs are assessed by first identifying which personnel within each program have QA-related responsibilities, what specific types of QA functions they perform, and at what frequency. These estimates are generally performed by the program' s Unit or Section Manager. The program Unit or Section Managers convey the specific QA training needs to the ADEQ QA/QC Unit. The ADEQ QA/QC Unit will develop an appropriate training program as a response to the training request.

3.1.3 Implementation of Training Requirements

ADEQ staff are encouraged by supervisors to draw upon their educational background, experience, technical training, and on-the-job training to enhance their understanding and performance of QA-related procedures.

The ADEQ QA/QC Unit will offer, or arrange for through a third-party vendor, the following four courses on a schedule and frequency suited to meet the needs of the ADEQ staff with QA responsibilities:

12. An Orientation to Quality Assurance Management
13. Establishing Data Quality Objectives
14. Preparing Quality Assurance Project Plans
15. How to Perform a Preliminary Data Review

Based upon ADEQ training requirements, no less than three of the four courses will be offered during the year and will be open to anyone responsible for QA functions. The ADEQ QA/QC Unit will also schedule impromptu QA training designed to address the specific QA needs of program staff.

ADEQ Program staff responsible for QA functions are expected to take, or have taken, all of the above courses within two years from their employ. In addition, they are encouraged to attend meetings and seminars, and to take formal training, in accordance with the ADEQ training policy, to enhance their understanding of program specific QA requirements within the programs they work.

3.1.4 Documentation of Training

The ADEQ Training Unit will maintain a record of all QA training taken by staff and managers responsible for environmental data generation. The ADEQ Management Team will provide resources for QA training for ADEQ program staff. This training will be provided, through internal training and/or external sources, to staff at all levels to ensure that QA requirements and responsibilities are understood and implemented at all stages of projects. Some of the training required to support the ADEQ Quality Management System program will come from EPA.

CHAPTER 4 PROCUREMENT OF ITEMS AND SERVICES

It is ADEQ policy that all activities involving ADEQ external oversight agreements and procurements for items and services be handled in the following manner:

Procurement of Items- The ADEQ Programs are required to define the quality of performance specification required of instruments and reagents. Although the ADEQ QA Unit is not generally involved in defining the performance objectives, the QA Unit will be consulted and provide input as appropriate.

Procurement of Services- Prior to the employment of outside contractor services to Agency programs arranged by the ADEQ Procurement Section, the ADEQ QA Unit will evaluate the prospective contractor to ensure said contractor has demonstrated a QA system and has a QA plan in place. The ADEQ QA Unit will define or evaluate QA systems and plans on a case-by-case basis. For example, the QA system in place may consist of Quality Assurance Program Plans (QAPrPs), Quality Assurance Project Plans (QAPjPs), SOPs, various types of audit procedures or a QA Officer.

In general, a Quality Management Plan (QMP) or its equivalent must be reviewed and approved by the ADEQ QA/QC Unit before the formal execution of any agreement or related action. As applicable, the contractors and subcontractors must also submit a Quality Assurance Project Plan (QAPjP) for the ADEQ QA/QC Unit' s review and approval before any environmental measurements or data collection activities can be performed.

Procurement activities may range from general and scientific supplies to highly sophisticated scientific instrumentation and services which directly affect the quality of environmental measurements. The procurement process is also governed by State statutes and rules, and depending on the circumstances of the procurement, may involve the approval of other agencies within the State. Within ADEQ, identified equipment needs are submitted to management who prioritize, rank and approve items for proposed procurement. This process allows ADEQ to identify particular equipment needs relative to other needs in order to facilitate quality in measurement processes. Specific monitoring, sampling and analytical equipment are procured only after quality requirements have been discussed between procurement officials, the ADEQ QA/QC Unit and program personnel.

4.1 CONTRACTS WITH EXTERNAL PARTIES

The ADEQ conducts and oversees assessment (site characterization), remedial, and removal activities at solid and hazardous waste sites in Arizona. For some of these activities, the ADEQ may contract directly for environmentally related measurements or data generation. Under a program mandated by Arizona Revised Statutes 49-360, ADEQ contracts with contractors to take samples and perform necessary analyses for approximately 900 small drinking water systems

within the State of Arizona. Other areas where contractors and subcontractors are utilized include: ambient surface water analyses for both chemical and microbiological indices, air quality analyses, etc.

4.1.1 The ADEQ/State of Arizona Procurement Process

The ADEQ public procurement process is guided by the Arizona Procurement Code (Arizona Revised Statutes 41-2501 et seq., and administrative rules and regulations A.A.C. R2-7-101 et seq.). This procurement code has modeled itself on the "Model Procurement Code" as provided by the American Bar Association.

The formal solicitation process at ADEQ and at the State Procurement Office, for statewide solicitations over $25,000, is generally as follows:

Pre-Solicitation Phase:

A need is identified by a customer and an initial meeting with Procurement is scheduled. A request is made for a vendor bid list from the State Procurement Office. Procurement personnel are required to use this bid list for all procurements over $25,000. In addition to the bid list, the solicitation is advertised. Letters of Intent are mailed to vendors who are on the Bid List. This letter of intent contains a brief description of the solicitation and other appropriate information. The Scope of Work is completed by the customer with input from Procurement as needed and incorporated into a Solicitation Package.

Solicitation Phase:

Evaluation committee members are selected/assigned. The make-up of this committee is comprised of the ADEQ customer(s), other state personnel with knowledge of the services and or products to be procured and if possible at least one individual from outside the Agency. An ADEQ Contract Officer chairs the meeting and may or may not be an evaluator. An evaluation planning meeting is scheduled. Evaluation committees come to consensus on all decisions regarding evaluation. This meeting involves discussing the method of scoring the relative importance of each evaluation factor and other related topics. The solicitation is mailed to vendors who have requested it. The solicitation states that any questions shall be forwarded to Procurement by a specific date and time. A meeting with the customer is set up to discuss the questions and answers. If a pre-proposal conference is scheduled, these questions and answers along with any other questions brought up at this meeting are discussed. Vendors are informed that the only official change to the solicitation will be forwarded in the form of an amendment and that they shall not rely on verbal changes/answers. If required, an amendment is forwarded to all vendors who requested the solicitation. Proposals are formally opened (with at least two procurement personnel in attendance) at the date and time stated in the solicitation. Late proposals are not allowed.

Pre-Award/Award Phase:

Procurement reviews the offers for compliance with requested information. At the first evaluation meeting, the proposals are distributed and evaluation committee assignments are assigned as appropriate. The members are given guidance regarding what to look for, how to score etc. Committee members are informed that they need to thoroughly evaluate all proposals and a second meeting is scheduled to discuss the proposals in detail. At the next evaluation committee meeting, the committee discuss their comments, scores and rankings of the offerors. A consensus regarding these comments and scores is reached. If appropriate, a Short List of the vendors who are most susceptible for award are selected. Discussions are held with these short listed offerors and the committee. These discussions may be written or oral. The evaluation committee discuss the answers and they may or may not change an offeror' s score. When the committee is satisfied that all questions are answered or clarified, discussions are ended and Best and Final Offer (BAFO) requests are sent to these vendors. The evaluation committee reviews and approves the BAFO. The Procurement Officer writes up all appropriate documents and awards the contract.

Post-Award Phase:

For blanket requirements contracts, the ADEQ Procurement Office issues Task Assignments to the appropriate Contractor. These Task Assignments are issued upon receipt of individual project assignments developed by an ADEQ Project Manager and approved by the ADEQ QA/QC Unit. In the event that the contractor does not perform in accordance with the contract, the state has several clauses to attempt to get the contractor to perform such as: 1) "Right to Assurance" clause where procurement may demand in writing that the contractor give a written assurance of intent to perform. 2) "Termination for Convenience" 3) "Termination for Default" and 4) "Right of Offset" which allows the state to collect monies due to a contractor' s failure to perform or due to non-conforming performance.

4.1.2 The Role of the ADEQ QA/QC Unit in the Procurement Process

Where contracts and related actions involve the collection of environmental data, the ADEQ QA/QC Unit and designated program staff shall be involved in the procurement process as follows:

Pre-Solicitation Phase: The ADEQ QA/QC Unit and designated program staff shall review statements of work and resources and provide language regarding QA tasks where appropriate and required. The ADEQ QA/QC Unit and designated program staff will provide information that incorporates, as needed, QA activities into the evaluation of sample work assignments, Quality Management Plan, and Quality Assurance Project Plans. The ADEQ QA/QC Unit also ensures that any laboratory solicitations adhere to the statutory requirement that all environmental laboratories performing compliance testing be licensed by the ADHS Office of Laboratory Licensure.

Pre-Award/Award Phase: The ADEQ QA/QC Unit shall serve on the evaluation committee for formal solicitations of laboratory services to evaluate the proposals

in general and to specifically evaluate and comment on specified QA submissions.

Post-Award Phase (Task Assignments): The ADEQ QA/QC Unit and designated program staff assist in monitoring task assignments which require Quality Assurance Project Plans and monitors QA activities. All task assignments related to the collection of environmental data shall be consistent with the program data quality objectives (DQOs).

4.1.3 The Role of the ADEQ Project Managers in the Procurement Process

The responsibility for monitoring contract performance within the ADEQ's Quality Management System includes, at a minimum, the following:

1. The ADEQ Program assigns a Project Manager.

2. The Project Manager or designee develops the project's Scope of Work. Project Manager edits if appropriate and forwards to the ADEQ QA/QC Unit for final review.

3. After award of a task assignment by the ADEQ Procurement Office, the Project Manager determines the relevancy of a post award meeting with the contractor.

4. All deliverables shall be sent by the contractor to the Project Manager to review, and approve/disapprove deliverables. If the deliverables are disapproved by either the Project Manager, designee, or the ADEQ QA/QC Unit, the disapproving authority shall contact the contractor and request clarification or a change in the deliverable in keeping with the contract.

5. Assuming that the contractor has made good on its contractual obligations to the satisfaction of ADEQ, an invoice is generally issued to the Project Manager or designee who authorizes the payment of the invoice.

6. If the contractor refuses or is unable to fulfill their contractual obligations to the ADEQ, the Project Manager or designee contacts the ADEQ Contract Officer who then either initiates actions to compel the contractor to perform or takes steps to terminate and reassign the task assignment.

4.1.4 Laboratory Licensure Requirements

In addition to the requirements of the Arizona Procurement Code (A.R.S. §41-2501 et. seq.) and the Arizona Administrative Code (A.A.C. R2-7-101 et. seq.), Arizona Revised Statutes require that the ADHS Office of Laboratory Licensure shall license environmental laboratories

engaged in compliance testing.

"Compliance testing has been defined by Arizona State Law pursuant to A.R.S. § 36-495(1) as any:

> "laboratory analysis of any matter, pollutant, contamination, hazardous substance or other substance subject to regulation pursuant to: A.R.S. § 36-495(1b) Federal environmental statues or regulations administered or enforced by the United States environmental protection agency relating to the ***safe drinking water act*** (42 United States code §§ 300f through 300j), the ***clean air act*** (42 United States code §§ 7401 through 7642), the ***clean water act*** (33 United States code §§ 1251 through 1376), the ***resource conservation and recovery act*** (42 United States code §§ 6921 through 6939B), the ***comprehensive environmental response, compensation, and liability act*** (42 United States code §§ 9601 through 9657) and the ***toxic substance control act*** (42 United States code §§ 2601 through 2654) as they relate only to the regulation of polychlorinated biphenyls and asbestos". (emphasis added)

Samples analyzed for regulatory or enforcement decisions by non-ADHS licensed laboratories will be considered unacceptable for compliance purposes, as statutorily mandated, and will be rejected.

Upon application for an environmental laboratory license, ADHS shall issue the license if after investigation, the department determined that the application conforms with the standards established by the department.

The ADHS director shall prescribe rules providing for minimum standards of proficiency, methodology, quality assurance, operation and safety for environmental laboratories and may prescribe standards for personnel education, training and experience to meet Federal environmental statutes or regulation, or enabling reciprocity with other states and the manner and form in which compliance testing results are reported. The rules shall be developed in cooperation with the Director of the Department of Environmental Quality and shall be consistent with Title 49 (Section 49-101 et seq.) and rules administered or enforced by the Director of the Arizona Department of Environmental Quality.

Unless exempted by A.R.S. §36-495.02, no person may operate or maintain an environmental laboratory without a license issued by the ADHS pursuant to A.R.S. §§36-495.03 through 36-495.14.

The ADHS State Laboratory Services (SLS) provides support for the ADEQ as necessary by testifying in court as to the validity of results generated by the State Laboratory on compliance samples submitted by ADEQ. Use of SLS eliminates any potential conflict of

interest on the part of the contracted laboratory.

4.2 AGREEMENTS WITH GOVERNMENTAL ENTITIES

The ADEQ also utilizes governmental agreements with EPA and other Federal, State and local agencies. A.R.S. §41-2501 exempts governmental agreements from the Arizona Procurement Code. Agreements between ADEQ and other state agencies or universities to provide or receive a service are authorized under A.R.S. §35-148, and agreements between ADEQ and another state agency or political sub-division or other governments to share joint authority (authority possessed by both parties) is authorized by A.R.S. §§ 11-951 through 11-952.

In the event that a governmental agreement scope of work would include environmentally related measurements or data generation, the ADEQ QA/QC Unit' s role would be substantially the same as described in 4.1.2. of the Pre-Solicitation Phase and the Post-Award Phase of this Chapter. Procurement' s role would include coordination with the ADEQ QA/QC Unit, the ADEQ Project Manager and the outside political subdivision, and final negotiation of the governmental agreement.

4.3 SMALL PURCHASES

Procurement of environmentally related measurements or data generation (laboratory services) which qualify for small purchases will be subject to Quality Assurance requirements by the ADEQ QA/QC Unit. In ADEQ, these actions are generally for specialized analytical services under which the laboratory is not currently under ADEQ contract. The Project Manager from the applicable ADEQ program shall contact the ADEQ QA/QC Unit and relate the needs and rationale for requiring outside analytical services. The ADEQ QA/QC Unit contacts the laboratory(s) and determines that the data quality objectives of the specific project as they relate to analytical requirements can be achieved by the laboratory. The ADEQ QA/QC Unit will also request that the laboratory submit a current Quality Assurance Program Plan (or similar documentation) for review **before the contract is awarded** by Procurement. Additionally, the Procurement Contract Officer will assure that there is a stipulation in the procurement action that a Quality Assurance Program Plan shall be submitted and approved by the ADEQ QA/QC Unit and designated program staff before any environmental measurements or data collection activities are performed.

4.3.1 Equipment Maintenance

The ADEQ field personnel are responsible for their respective maintenance of field equipment and instrumentation. The ADEQ has either service contracts or in-house capabilities for the repair and maintenance of field equipment and instrumentation. Schedules for preventive and/or corrective maintenance are determined and carried out through service contracts or in-house capabilities.

CHAPTER 5 DOCUMENTATION AND RECORDS MANAGEMENT

Maintaining important quality assurance (QA) documents and records is a continuous process at ADEQ. This process serves as a vehicle for identifying quality-related documents and records requiring management control. Moreover, this process serves to assure that QA documents and records are accessible and protected in storage from damage and deterioration. Finally, the ADEQ Records Management Process ensures compliance with all statutory and contractual requirements for records involving environmental programs. The ADEQ Records Management System also provides adequate preservation of key records necessary to support the mission of ADEQ.

5.1 DEFINITION OF PUBLIC RECORDS

ADEQ policy #0033.001 Public Access to Public Records (see Appendix D) defines public records as all records reasonably necessary or appropriate to maintain an accurate knowledge of the official activities of the department. Public records are made or received in the conduct of Agency business. They relate directly to the function of an office and they documents those functions. A record is any recorded information relating to the work of your office — regardless of who created it or how the information was recorded. Most records are paper documents, such as letters, memos, completed forms, directives, and reports. Records may also be non-paper such as: photographs, maps, microfilm, audiotapes, videotapes, and computer tapes or disks, etc. All these require special care, particularly information created or stored on a computer or word processor. These records can only be disposed of using authorized records control schedules.

5.2 MATERIALS EXCLUDED FROM THE DEFINITION OF PUBLIC RECORDS

Materials excluded from the definition of public records include reference material, extra copies of articles, periodicals, reports, documents, blank forms, extra copies of documents preserved for convenience of reference, studies, vendor catalogs, and similar materials that are needed for convenience or reference but are not part of the official file. Such items should be destroyed as soon as they are no longer needed.

Other materials excluded from the definition of public records include draft documents including electronic and marked up copy drafts.

5.3 CONFIDENTIAL DOCUMENTS

Some documents collected, received, or generated may, by nature and content, be documents which require special handling procedures. Documents of this category may be, but are not limited to, enforcement sensitive/enforcement confidential, attorney client, or confidential business information (CBI). Confidential documents are handled in accordance with the ADEQ Policy #0032.001 Confidential Records (see Appendix E). Only ADEQ staff are allowed to see documents classified as enforcement confidential. Confidential documents shall be maintained separately from other QA documents. Only those ADEQ staff and others who have been trained and authorized can access CBI files.

In most cases criminal sanctions exist for unauthorized disclosure of CBI. Nothing in the requirements put forward in this QMP shall be construed to supersede any existing requirements for handling enforcement sensitive or confidential documents.

5.4 ROUTINE QUALITY ASSURANCE AND RECORDS MANAGEMENT

The ADEQ Records Management Process addresses the system employed by the Agency for handling documents. This plan outlines the roles and responsibilities for management and staff concerning chain of custody procedures and records management.

ADEQ document control procedures require that documents generated by or obtained by our Agency personnel will be accounted for when a project is completed. The ADEQ' s Records Management System dictates the procedures for checking-in and checking-out files for ADEQ staff as well as for external clients and the public.

A unique identification code is created by ADEQ for each investigation or project and a cross reference to the codes generated by those entities which submit data and other records to which ADEQ is assigned. Any custody tags, custody records, field notes and analytical records are labeled with the ADEQ generated codes. Each record is required to have a project number, date, the Agency Project Manager' s initials or signature and the ADEQ INDEX and PCA codes. Data packages generated by laboratories which are requested by Project Managers and submitted to the ADEQ QA/QC Unit will be maintained by the ADEQ QA/QC Unit.

Project or site specific QA documents and other records generated are stored in the applicable program offices within the ADEQ or in the Central Records Management Office. ADEQ is in the process of transitioning to centralized agency record management. However, only Phase I of the transition has been completed. Regardless of physical location of a file, records and documents associated with a given project are the responsibility of the Division Program that has primary responsibility for that project. Hard copies of site or project specific information such as sample field sheets, chain of custody records, laboratory notes, and instrument/equipment readings shall be maintained in the official project file. The ADEQ Project Manager is responsible for assuring that all field and analytical identification codes referencing the project are maintained in the project file. The ADEQ Director represents the final custodian of

that information.

Projects involving the generation of environmental data shall include, as a minimum, the Quality Assurance Project Plan (QAPjPs) and final laboratory reports. QAPjPs submitted to ADEQ are peer reviewed by the respective Project Manager, the ADEQ QA/QC Unit staff and designated program staff. Approved copies having the approving signatures are retained by the program' s Project Officer and the ADEQ QA/QC Unit. The QAPjP and the final analytical reports will be stored together, thereby allowing a subsequent analyzer (ADEQ QA/QC Unit or designated program staff) or investigator to understand the full context of the data produced and the conclusions reached.

The ADEQ QA/QC Unit in conjunction with EPA Region IX ensures that all Quality Management Plans and Quality Assurance Project Plans are current. Should one of these documents become outdated, the ADEQ QA/QC Program Supervisor and EPA Region IX, in conjunction with the ADEQ Project Manager, shall determine the status of the plan and initiate appropriate action. The Division Program and the ADEQ QA/QC Unit shall be responsible for maintaining copies of the ADEQ revised/approved QAPjP for five years after completion of the project.

The ADEQ management will assure that the objectives of the Records Management Process are achieved. These objectives include the following:

Prevent the creation of unnecessary records in any media;

Promote the continuous development of filing systems and structures that allow for the efficient organization, maintenance and retrieval of records;

Ensure that records of continuing value are preserved but that valueless or non-current information are disposed of or transferred to storage in a timely manner in accordance with ADEQ disposition schedules or ADHS records retention requirements;

Ensure that the acquisition and use of all direct paper to microform systems and equipment or electronic digital image are technically feasible, cost-effective, and most importantly, satisfy program needs; and,

Preserve and protect information that is vital to the essential functions or mission of the organization. Preserve and protect information that is essential to the legal rights and interests of individual citizens and the government.

5.5 IN-HOUSE QUALITY ASSURANCE GUIDANCE DOCUMENTS

Quality guidance documents developed in-house are peer reviewed by the ADEQ QA/QC Unit and the appropriate divisional program. Most of the in-house quality guidance documents

are formatted as SOPs covering specific environmental monitoring activities such as field inspection, sample collection/handling, analytical protocols, and data review/validation. The ADEQ QA/QC Unit has developed, to date, field sampling protocols for the collection of water samples from Arizona public water systems that will be submitted to ADHS certified laboratories for the analysis of volatile organic compounds (VOCs), synthetic organic compounds (SOCs), and inorganic compounds (IOCs). These SOPs have been peer reviewed and approved by EPA and the ADHS State Laboratory for ADEQ use.

Other in-house quality assurance guidance documents include policies. The ADEQ QA/QC Unit drafts quality assurance and analytical policies to express the Agency' s position when interpreting analytical data generated by laboratories using EPA methods which may have multiple procedural interpretations. Two such agencywide policies are ADEQ Policy # 0154.000 Addressing Spike and Surrogate Recovery as They Relate to Matrix Effects in Water, Air, Sludge and Soil Matrices and ADEQ Policy # 0155.000 Analytical Methods Having Provisions for a One-Point Calibration and Continuing Calibration Verification Constraints.

5.5.1 Requirements for Field Documentation

Documentation of field activities establishes procedures; identifies written records; enhances and facilitates sample tracking; standardizes data entries; and, identifies and establishes authenticity of the sample data collected. Proper documentation helps to ensure that all essential and required information is consistently acquired and preserved. Timely, correct, and complete documentation establishes the chain-of-custody, a requirement for data intended for use to provide evidence for court proceedings.

Field records shall be generated and stored as specified in project specific QAPjPs and SOPs. Guidance for handling field records is provided in the June 1994, Region 8, "***Standard Operating Procedures for Field Sampling Activities***" and its subsequent revisions.

5.6 MAINTAINING DOCUMENT INTEGRITY

Following all required ADEQ documented policies and action regarding Records Management, the file clerk and all other ADEQ staff with access to sensitive or potentially sensitive documents and records (i.e., audit reports and performance evaluation reports) will take special care to preserve the integrity of these documents. If sensitive documents are to be used at a work station, due care will be used there, too, in order to maintain the integrity of the data.

CHAPTER 6 INFORMATION TECHNOLOGY AND DATA MANAGEMENT

In order to ensure effective and efficient use of the ADEQ' s hardware and software system design, development, implementation and maintenance, the ADEQ will attempt to comply with all EPA standards and regulations pertaining to hardware, software, system development and data. It is the goal of ADEQ to achieve consistency in the way data are generated, compiled, stored and disseminated across each of the Divisional (Air, Waste and Water) programs.

There are five major kinds of environmental information management activities conducted at the ADEQ:

1. Planning the project;
2. Gathering the data;
3. Managing the data;
4. Disseminating the data; and,
5. Evaluating results.

These activities occur in sequence, with the understanding that each activity can be adjusted to reflect changing conditions and project results. Other activities should occur throughout the lifetime of a project, as follows:

Communication;
Quality assurance;
Cost control; and,
Security.

This section focuses on the information management aspects of Agency project-management and data dissemination protocols and also identifies the roles and responsibilities that the ADEQ Office of Information and Technology (OIT) provides as an infrastructure. It does not address the other aspects of project management-planning, data gathering, and evaluation provided by the ADEQ programs which will be addressed in the QAPrPs.

6.1 MANAGEMENT PRACTICES FOR ENVIRONMENTAL DATA

Documenting the Project: ADEQ utilizes a standard System Development Lifecycle Methodology for information projects. This methodology includes a full analysis and documentation of user requirements followed by design specifications. ADEQ uses the Oracle Designer tool to document requirements and system design. Agency coding standards are published and implemented which ensure consistency and maintainability of source code. A "project team approach" is utilized which includes end user involvement throughout the project lifecycle. User documentation, including on-line help, is provided with each system as resources permit.

Establishing Back up and Archiving Procedures: Each program will coordinate with the Office of Information and Technology to establish standard procedures for data backup and archiving, system failure, and recovery. Data sets will be archived to provide a historical record of data over the lifetime of the project. Current procedures involve daily full and incremental backups of all critical agency data, that are stored on site at ADEQ. Weekly and monthly back up of all critical data are kept in perpetuity and stored off site in the State' s archive facility. The agency is working with the State to identify and develop "Hot Site" hardware capabilities which will provide additional hardware located off-site that can be used to process data in the event that the primary hardware is destroyed. The "Hot Site" can be thought of as an additional server room located off the main premises.

Ensuring Data Integrity*:* Ensuring data integrity involves addressing the vulnerability of the system to unauthorized access, data manipulation, theft, and environmental damage. Key potential threats include:

1. Inappropriate/inaccurate information - Project workers can supply inappropriate or inaccurate information accidentally or on purpose.

2. Compromised information integrity - Documents or data can be accidentally or intentionally modified.

These threats are mitigated by implementing a strong internal quality assurance/quality control process.

The Central Data Management Group (CDMG) maintains the ADEQ' s centralized core data for Licensing Time Frames (LTF), PLACE (the sites and facilities that ADEQ regulates or tracks), and CUSTOMER (individuals, organizations and businesses that ADEQ regulates or interacts with) databases within Arizona Unified Repository For Informational Tracking of the Environment (AZURITE). CDMG enters the core data for all license applications that are subject to the LTF statute and rule, plus all Places and Customers that ADEQ tracks expenditures for or against in the Arizona Financial Information System (AFIS).

Currently, core data are entered and updated only by CDMG personnel, based on information provided by the administrative and technical programs. Data entry standards have been established to give entry users clear guidance when entering data. To assure compliance with the data entry standards, CDMG runs validation reports on new records entered into these systems to assure the data are complete and that a duplicate record for a place or customer does not exist.

At the point when administrative and technical staff begin entering core data into the shared databases these records will be validated by CDMG. Any record that is not complete will be returned to the originating program for correction, and usage of that data will be restricted until it is corrected.

Presenting Data In An Understandable Format: Agency projects will be presented in a way that is suitable for the intended audience. The following guidelines are implemented by

ADEQ, to the extent applicable, useful and possible, in designing effective approaches in agency projects:

Establish a context for presenting data - methods for illustrating context include displaying data in a geographic context, combining the new data source with existing collections of monitored data, or aggregating the data collected to demonstrate a trend or ongoing view of the environmental conditions. ADEQ Programs will present the data in ways that make that data relevant and useful.

Format data for easy interpretation - Environmental data can be interpreted in many different ways. The Agency will make a supreme effort to ensure that data will always be presented in a format that is easy to understand and not subject to misinterpretation.

Be responsive to the users of the data - To keep abreast of changing user needs, the Agency projects are designed in ways for users to provide feedback on the projects.

Ensuring Data Quality: All Agency projects will consider three key items: quality assurance analysis, systems development planning, and audits and testing.

1. Quality assurance analysis - The type of QA effort needed depends on the qualitative and quantitative criteria that the data must meet and on the complexity and magnitude of the project. The Agency will establish the ultimate needs and objectives for the data quality in the early planning stages of the project.

   CDMG will maintain and assure that data entry standards are followed, that locational information is provided and that a duplicate record does not exist before validating a new record as part of Agency core data. Any record that is not complete or does not meet data entry standards will be returned to the originating program for correction and the use of that data will be restricted until corrected.

2. Systems development planning - The State of Arizona utilizes a standard Information Technology (IT) project planning and justification process. The Government Information Technology Agency (GITA) reviews and approves Project Investment Justifications (PIJ) for projects with greater than $25,000 development costs and infrastructure hardware. PIJ approval must be received before budget monies can be allocated to a project. The central IT organization work in unison with the decentralized Program IT units to plan, prioritize and implement agency IT projects.

3. Audits and Testing - All IT projects involving development of systems for tracking of environmental data will be thoroughly tested to ensure that they meet the requirements in the written functional specifications. Independent audits of these systems will be conducted by the Laboratory and General Services section. The central IT organization has a UNIX and NetWare Test server environment that is in place and is

utilized regularly to test agency applications prior to being released into production.

6.2 INFORMATION MANAGEMENT PLAN

The ADEQ has an information management plan that documents our approach to data collection, storage, retrieval, delivery, and communication and procedures for data quality control and security, which may be incorporated, as appropriate, into our organization' s Quality Assurance Program Plans.

The information management plan includes the following elements:

Data Owner(s) – ADEQ has a Centralized Data Management Group (CDMG) which has been assigned the responsibility of maintaining core data. Core data are those data which are shared across programs such as site/facility data and customer data. CDMG' s ownership of these data provide a clear line of authority and responsibility for quality assurance. Non-core data are owned by the programs. This information plan provides the primary contact information of the individual and program that has overall information management responsibility and authority for Agency projects.

Description Of The Data Flow Process – The plan explains the key points in the information data flow and collection process. This can be illustrated by a flow chart or diagram depicting key information components.

Description Of The Data Collection Methods – The plan summarizes data measurement and collection methods. It also describes any emerging measurement technologies used and/or how existing systems of environmental monitoring will be augmented/up-graded to provide the proposed data.

Description Of The Data Storage And Retrieval System – ADEQ' s standard relational database platform is Oracle. The ADEQ utilizes Oracle tools including Designer and Developer for application development. and Microsoft Project for planning and tracking projects to completion. The plan describes the hardware and software technologies that will be used for data management and processing systems. It specifies the components of the project architecture and also describes the archival components or storage capabilities. The plan addresses data management responsibilities among stakeholders and contractors to ensure data documentation and data standardization. For all non-ORACLE applications the agency uses a Novell NetWare and UNIX network.

6.3 LEVELS OF DOCUMENTATION FOR ENVIRONMENTAL PROJECTS

Documentation is important because it helps users to make informed decisions regarding

the use of the data, provides consistency and project "memory" over time, and allows the data to be shared and used in a variety of computing environments.

The ADEQ has developed the following four kinds of documentation requirements for environmental projects:

16. ***Project Documentation****:* Documenting critical information about the project, including the project purpose and scope, the user requirements, the project investment justification and the project plan;

17. ***Data Set Documentation:*** Clear information about what data are collected and how to access and use it;

18. ***Data Element Documentation:*** Full definitions and specifications for each element collected and maintained in a data set; and,
19. ***Database System Documentation:*** Electronic and hard copy documentation of system design and implementation.

6.4 COMPUTER HARDWARE/SOFTWARE REQUIREMENTS

ADEQ managers and Office of Information and Technology staff will comply with all hardware and software standards delineated in the agency' s software and hardware standards that are maintained by OIT. These standards address compatibility, hardware, operating systems, communication, database management, user interface/printer interface, application development and applications.

The ADEQ will procure hardware and software that conforms to agencywide and EPA information management architecture. In some cases, the ADEQ will buy or develop hardware or application software that is not on the Statewide contract. All such purchases will be evaluated to ensure that they comply with ADEQ standards as outlined in the Agency' s software and hardware standards. Prior to any purchases, the ADEQ Chief Information Officer, or delegated assignee, will evaluate software and hardware to determine its performance capabilities and the impact of implementation upon ADEQ and reporting requirements to EPA.

6.5 SYSTEM DEVELOPMENT

All ADEQ system development, enhancement and modernization efforts will comply with Agency standards. This compliance will include a systematic and comprehensive dialogue between the data providers, data/system users and system developers, prior to the design of the system in order to ensure successful extensive user participation and a systematic approach to the design. Systems will be designed and built to integrate to core agency data in such a manner that re-use of code is a priority and efficiencies are maximized.

All software systems shall be operated and maintained in accordance with the written specifications or owners manual. All software systems will be subjected to acceptance testing by end users prior to being placed into a production environment.

For the proper implementation and maintenance of the technology infrastructure, the ADEQ Office of Information and Technology is developing:

> An inventory of the computer system(s) hardware and written operating procedures for routine maintenance operations;
>
> Documents describing data management systems in use, including functional and design specifications and requirements; and,
>
> Standard Operating Procedures which describe routine operation, maintenance and testing to ensure that both the hardware and software in use are accurately performing the intended functions.

These documents will be readily available in the areas where these procedures will be performed. Changes in any part of the operating procedures shall be properly authorized, reviewed and accepted in writing by the designated responsible person.

6.6 DATA STANDARDS

To take full advantage of both ADEQ' s and EPA' s growing technological and data standards and resources, there must be an increased emphasis on improving the compatibility of data among computer systems. Federal data policies and standards that currently are followed, including those which ADEQ is attempting to implement, include:

> Chemical Abstract Service Registry Number Data Standard, EPA Order 2180.1, June 26, 1987;
> Data Standards for the Electronic Transmission of Laboratory Measurement Results, EPA Order 2180.2, December 10, 1987;
> The Minimum Set of Data Elements for Ground Water Quality, Policy Order 74500.IA, September 11, 1989;
> Facility Identification Data Standard, U.S. EPA Office of Administration and Resources Management, Information Management and Services Division, April 9, 1990.
> Policy on Electronic Reporting, U.S. EPA Office of Administration and Resources Management, July 30, 1990;
> Site Location Identification Policy and Responsibilities, Region III, Order 5361.5, September 14, 1988;
> ADEQ Locational Data Policy, 0034.001 (see Appendix J);
> Locational Data Policy, IRM Policy Manual, Chapter 13, April 1991; and
> Locational Data Policy Implementation Guidance- Guide to the Policy, U.S. EPA

Office of Information and Resources Management, March, 1992.

6.7 INFORMATION SECURITY

It is important that the ADEQ information resources are protected from potential loss and misuse from a variety of accidental and deliberate causes. ADEQ utilizes the following security procedures and protocols:

Network Operating Systems uses log in and password controls;
Internal rights to agency data are granted by local management for their employees
A firewall security system exists for Internet usage;
Remote access controls for employees and third parties -- uses log in and password protection;
All UNIX, NetWare and Remote Access Operating Systems comply with DOD C2 security standards; and
The main computer room is physically secured for access by only critical IT personnel.

CHAPTER 7 PLANNING

A primary goal of the ADEQ' s Quality Management System is to promote the effective planning for the collection, analyses and processing of environmental data. Quality planning must occur at three levels to ensure that such data meets the ADEQ programmatic and quality goals for:

Agencywide Requirements;
Program Specific Requirements; and,
Project Level Requirements.

7.1 AGENCYWIDE PLANNING

7.1.1 Internal Strategic Planning

The ADEQ Strategic Plan is the foundation upon which all programmatic priorities and corresponding environmentally related data collection and use activities are based. Using the projected annual budget for ADEQ from the various funding sources including EPA and the State of Arizona, the ADEQ Director and senior managers usually meet early during the fiscal year to discuss and set ADEQ priorities. These priorities are then reflected in the ADEQ Strategic Planning process, which establishes overarching goals, direction, resource utilization policies and budget allocations. Yearly action plans developed by the individual ADEQ Divisions, tied to the ADEQ Strategic Plan and budget distribution process, further specify the types of environmentally-related data generation activities that will occur. The yearly action plans also dictate what decisions they are designed to support and the corresponding requirements for quality assurances and quality control procedures.

7.1.2 External Data Coordination

The ADEQ must also coordinate the collection and use of environmentally related data across numerous government agencies, and also academic and private organizations. Close coordination and planning is essential to ensure that data are of sufficient quality to support decision-makers or otherwise meet the intended uses and can be shared where Data Quality Objectives (DQOs) are similar. The ADEQ encourages data sharing whenever possible, provided that adequate data quality indicators (DQIs) are available so that the quality of data are sufficiently known to support the applicable decision(s).

7.2 PROGRAM-SPECIFIC PLANNING

The ADEQ Programs are functional areas of work authorized by Statutory reference (e.g., Air Toxics Program or Drinking Water Program) or by Agency direction (the Voluntary Remediation Program). Any of the ADEQ environmental programs which generate

environmental data are covered by the QMP, though it is acknowledged that not every program or project requires the same level of quality assurance. Generally, program managers (their grades and titles vary by Division) are responsible for program level planning, which includes the responsibility to ensure that there is agreement between the customer and the data supplier as to expected data quality.

Developing Data Quality Objectives (DQOs) when initiating a new project or incorporating major statutory changes is a mandatory component of the ADEQ Quality Management System. The EPA Quality Assurance Division guidance document "***Guidance for the Data Quality Objectives Process***" (EPA QA/G-4) is available to assist users in developing these objectives as are resources within the ADEQ QA/QC Unit. DQOs at the project level include all sources of error (i.e., design, sampling, measurement, or indicator error) that will accumulate and affect the interpretation of data for status and trends. Program-level DQOs are defined by their ability to meet Division program objectives. Data Quality Objectives are also used as performance criteria for assessments of data quality for their adequacy in determining status and trends.

It is critical to consider the QMP as part of the planning process when modifying existing programs or designing new programs. Although the QMP outlines the minimum QA requirements for the ADEQ, it is likely that most of the programs covered by the QMP will need more QA specificity and detail for implementing their programs. In these cases, supplemental QA components and procedures should be developed and described by the program in conjunction with the ADEQ QA/QC Unit. The ADEQ QA/QC Unit will serve as technical advisors in the development of these procedures and documents. All programs covered by the QMP should review their programmatic requirements within the next year to determine if the QMP adequately covers their QA needs, and develop supplemental procedures as identified.

7.3 PROJECT-LEVEL PLANNING

A project is an organized set of activities within a program. The Quality Assurance Project Plan (QAPjP) is the primary vehicle for ensuring that adequate data quality at the project level (see Chapter 2, Section 2.2 and 2.2.1 for a more complete discussion of the QAPjP development and review process). The ADEQ QMP refers to QA activities as a well-defined component of any project plan involving the collection or use of environmental data.

The key to good quality planning at this level is to link the data collection or analyses to be performed directly to the environmental decision to be made. This is essential so that the ADEQ does not collect mounds of data for which there is no purpose. Achieving this key component requires dialogue between the decision maker, contractor and the data supplier. Again, the EPA Quality Assurance Division (QAD) document EPA QA/G-4, "***Guidance for the DQO Process***", as well as resources within the ADEQ QA/QC Unit, can be invaluable in establishing the desired data certainty requirements based on the decision to be made.

The use of statistical methods to quantify data acceptability measures is highly

recommended. Members of the QA Team in EPA Region IX can provide assistance with statistical applications. The ADEQ QA/QC Unit can assist ADEQ Programs by providing the appropriate references.

Planning documentation should identify the ADEQ personnel responsible for ensuring that all components of a QAPjP are addressed appropriately. Project Managers will normally be responsible for the development of these QA components, which will adhere to the requirements of EPA QA/R-5, "***EPA Requirements for Quality Assurance Project Plans for Environmental Data Operations***." When QAPjPs are submitted by the ADEQ Project Manager to the ADEQ QA/QC Unit for review and approval, the ADEQ QA/QC staff will be responsible to ensure that all the required elements in the QAPjP are appropriately addressed.

When initiating a site-specific project, the ADEQ program staff shall develop a preliminary plan for accomplishing the required work. Through this process, specific individuals are made accountable for different aspects of the investigation.

The ADEQ planning process takes into account:

Identifying the regulations involved;
Defining the forensic requirements of the regulations;
Structuring communication between all the parties involved in the project;
Defining the scope of the project to meet enforcement objectives;
Identifying and scheduling activities;
Identifying resources needed;
Identifying health and safety issues; and,
Questioning the validity of scientific models and methods proposed for use.

7.3.1 On-Site Monitoring

The determination to use on-site monitoring, and the specific type of monitoring to be conducted, is based upon the project objectives as defined by the QAPjP for a monitoring program and the type of field conditions encountered.

Field screening information, combined with statistics, can be used to define the number and type of samples needed to meet the project objectives.

Monitoring for personal protection might include using a specific instrument to screen the work area to determine the appropriate level of personal protection needed. These instruments can also be used for continuous monitoring while work is being performed.

Quality control indicators used in on-site monitoring depend on the applicable regulations, the type of equipment, the nature of the materials monitored, and the monitoring objectives. Quality control parameters such as blanks, blank spikes, matrix spikes, field duplicates, surrogates and calibrations curve data (all QC parameters as they apply) shall be documented.

7.3.2 Sampling Events

The sampling activity shall be focused toward meeting the regulatory, technical and analytical requirements defined during the planning phase. ADEQ sample collection activities are designed to answer questions such as:

How does the material compare to a regulatory threshold?
How does the material compare to another?
Is a component/condition present?
Are there trends or hot spots?

The sampling activity requires:

Coordinating field activities with laboratory activities;
Maintaining sample integrity; and,
Focusing on regulatory and agency defined data quality requirements.

7.3.2.1 Sample Scheduling

All laboratory sample scheduling events by the ADEQ through non-ADEQ laboratories must be coordinated through the ADEQ QA/QC Laboratory Coordinator. The ADEQ QA/QC Unit will communicate with ADEQ Program Managers or with the Arizona Attorney General' s Office to ensure that the analytical requirements of the Agency' s data quality objectives can be fulfilled. The communications will include the matrix types, required detection limits and identification of the Federal or State statutes under which ADEQ intends to regulate.

7.4 ANALYTICAL REQUIREMENTS

Analysis involves the characterization of samples based on chemical and/or physical properties. Analysis results in generating raw data from either instrumental analysis, chemical analysis, or physical testing. The analytical methods used will be specific and sensitive enough to answer the question posed by the enforcement objectives and meet the data quality goals associated with those objectives.

ADEQ Project Managers may consult with the ADEQ QA/QC Unit or research a variety of published or written materials to aid them in selecting or developing measurement technologies. The ADEQ QA/QC Unit shall maintain a file of in-house procedures and practices used in the measurement process. Data Quality Indicators (DQIs) and the ADEQ QA/QC Unit' s professional knowledge are used to identify instances which require particular analytical procedures.

7.5 DATA TRANSLATION

Data translation involves translating raw data into useable information which can include qualitative identifications, quantitative determinations, and/or statements of condition. This process can include arithmetic calculations and statistical evaluations of results from a sample or collection of samples.

7.6 DATA INTERPRETATION

The Project Manager, with input from technical staff and the ADEQ QA/QC Unit, will attempt to use sample data to form an opinion about the characteristics of a data set. The ADEQ Project Manager will use the quality control indicators incorporated into sampling and analyses to support opinions or to identify limitations of the data. The ADEQ QA/QC Unit will be available to assist the ADEQ Project Manager in assessing data quality indicators when actions have regulatory implications. The characteristics of the data set will then be compared to regulatory requirements to determine compliance.

7.7 HEALTH AND SAFETY

Health and safety are an integral part of the ADEQ Quality Management System, because the management philosophy is that a safe workplace is essential for the long term success of the Quality Management System. ADEQ Management, with the assistance of the ADEQ Health and Safety Officer, developed policies and procedures focused toward a safe working environment, and developed a program that is adequate to protect the health and safety of ADEQ staff. The ADEQ Health and Safety procedures implement applicable EPA and Office of Safety and Health Administration regulations. The ADEQ Safety Officer conducts, our contracts for, specialized training programs to meet the safety needs of ADEQ measurement activities.

The ADEQ Health and Safety Environmental Management Program is the mechanism which ensures that appropriate issues are considered prior to the initiation of measurement activities. The ADEQ Health and Safety Environmental Management Program includes the following three key elements:

20. Training - Includes field and laboratory safety, first aid and CPR, driving safety, supervisory safety training, office safety, hazardous waste training, and other pertinent training.

21. Audits, Inspections, Investigations, and Hazard Control - Includes planning reviews and associated reporting and record keeping to identify, prevent, and/or abate health and safety problems.

22. Occupational Medical Monitoring - Includes medical monitoring of staff who may be exposed to chemical, biological, radiological or other agents, or who may experience physical stress during their work.

CHAPTER 8 IMPLEMENTATION OF QUALITY ASSURANCE WORK PROCESSES

This Chapter of the QMP describes the processes used at the ADEQ for ensuring that the QA plans and procedures which comprise the ADEQ Quality System are effectively implemented. Any changes to the QMP will be documented in revisions and will receive the same level of review and approval as the original document. As with the QA planning described in the Chapter 7, implementation of QA procedures takes place at the Agency, program and project levels.

8.1 AGENCYWIDE IMPLEMENTATION

The ADEQ utilizes a decentralized approach to ensure that environmental data are of sufficient quantity and quality for its intended purpose. Any revisions to the QMP will be processed in the same manner as was the original document. QMP revisions will be drafted by the ADEQ QA/QC Unit, and submitted to the ADEQ Leadership Team for approval. The ADEQ QA/QC Program Supervisor will provide general oversight of implementation of the ADEQ Quality Management System. The ADEQ Divisions and Programs will provide technical oversight for implementing environmental data operations through the development of Quality Assurance Program Plans (QAPrPs).

8.1.1 Divisional Quality Assurance Program Plans

Each ADEQ QAPrP will be approved by the ADEQ QA/QC Unit and will address the process for implementing environmental data operations according to the approved planning documents. Additionally, each QAPrP will identify those specific activities that will ensure the generation of quality data by:

Identifying the mission elements and/or programs generating or using data for environmental decisions;

Identifying criteria for collecting or selecting data sufficient to support environmental decisions;

Describing procedures for the preparation, review and approval of QAPrPs;

Outlining procedures to ensure that the work described in the QAPrP is being performed according to the Plan, including evaluation activities;

Ensuring that individuals with QA responsibilities have been properly trained; and,

Defining the level of management oversight to be provided that will be commensurate with the importance of the particular project and the intended use of the project results.

Each ADEQ Divisional QAPrP is scheduled to be reviewed by the ADEQ QA/QC Unit each year after initial approval to ensure the plans accurately reflect how business within the program is conducted.

8.2 PROGRAM LEVEL IMPLEMENTATION

8.2.1 Operating Policies and Procedures

Any ADEQ program which generates or uses environmental data will document their responsible QA policies and procedures and will develop and/or use appropriate policy and procedures manuals for their programs. The ADEQ QA/QC Unit will provide support and oversight in the generation of such documents. The EPA Quality Assurance Division (QAD) document "***Guidance for the Preparation of Operating Procedures for Quality-Related Operations***", QAD/G-6, November, 1995, should be referenced by ADEQ programs and the QA/QC Unit for developing procedures manuals for administrative and technical QA operations. Having these procedures available will ensure that program personnel are knowledgeable about their operations, and will also serve as a training guide for new staff members.

The ADEQ QA/QC Program Supervisor will work with the ADEQ programs to ensure that operational QA policies and procedures developed by the programs are consistent with the ADEQ QMP. This responsibility includes defining procedures for appropriate routine, standardized, special, or critical operations, including the policies and procedures that address, but are not limited to:

The identification of operations needing standardized procedures;

The process for preparation of procedures, including form, content, and applicability; and,

The review and approval of the adequacy of the SOPs.

Any QA procedure manuals developed by the ADEQ QA/QC Unit will be made available to all personnel involved in program implementation. If implementation of the program is delegated, the manuals will be referenced in any assistance or delegation agreement consistent with the ADEQ Procurement process. Where a program uses data generated by external sources, it must develop criteria and a process by which to evaluate the acceptability of the data supplied, in the context of the environmental decision(s) to be made. The data quality assessment process described in Chapter 9.4 can be useful here.

8.3 PROJECT LEVEL IMPLEMENTATION

8.3.1 Quality Assurance Project Plan Implementation

All environmental data operations will be implemented in accordance with an approved

QAPjP. Any changes to the QAPjP will be documented and approved in writing through an amended QAPjP. Amendments will be reviewed and approved by the original approving officials (ADEQ Project Manager and the ADEQ QA/QC Unit). The ADEQ Project Officer should include identifiable QA milestones and target dates in the project timeline so that progress and completion of QA and QC activities can be effectively tracked.

For contracts and grants involving environmental data generation, the ADEQ Project Officer and ADEQ QA/QC Unit shall ensure that the applicable Task/Work Assignment, Task/Delivery Order or similar document includes specific requirements for reports on the QA of products or services to be supplied.

8.3.2 Standard Operating Procedures (SOPs)

Many repetitive procedures that are routinely used can be standardized and documented in writing as standard operating procedures (SOPs). SOPs can be prepared for routinely conducted sampling, analytical, and quality control procedures. Once established, the SOPs can be cited in the QAPjPs, contract proposals, grant agreements, and other similar documents, thus saving time and paper by avoiding the need to write out the specific procedures in each document. ADEQ SOPs relating to QA shall be reviewed and approved by the ADEQ QA/QC Unit and maintained by the appropriate program office. Any substantive changes in the SOPs will be likewise approved by the ADEQ QA/QC Unit. Tasks or functions that may be effectively addressed within a SOP include:

Sampling network design;

Sampling site selection;

Sampling and analytical procedures;

Sample collection methods and devices, containers, preservatives, holding times, handling and transportation methods;

Documentation and chain-of-custody procedures;

Calibration and maintenance of instruments and equipment;

Quality control procedures;

Data review, reduction and validation;

Safety procedures; and,

Inspection and audit procedures.

CHAPTER 9 QUALITY ASSESSMENT AND RESPONSE

This Chapter of the QMP describes how the ADEQ will assess the effectiveness of its Quality Management System. The ADEQ will use a variety of internal management and technical reviews, performance evaluations and QA audits to make sure that the procedures in this QMP are implemented successfully. The ADEQ will also utilize, as needed, independent reviews of the systems and procedures described in the ADEQ QMP by personnel from the EPA Region IX Quality Assurance Division. This chapter will also describe the ADEQ' s commitment to using the results of these evaluations to make any necessary operational adjustments to the ADEQ' s data collection and analytical procedures, as well as to other aspects of the Quality Management System.

9.1 ANNUAL REVIEW OF THE QUALITY MANAGEMENT PLAN

The QA practices and procedures described in the QMP will be assessed annually and revised or updated on October 1 of each year by the ADEQ QA/QC Unit. The ADEQ QA/QC Program Supervisor is responsible for coordinating this assessment, arranging for appropriate personnel to assist with the review, and for incorporating any recommended changes into the QMP. Minor changes in the QMP proposed by the ADEQ Programs should be submitted in writing to the ADEQ QA/QC Supervisor by June 30th of each year.

9.2 QUALITY AUDITS

The ADEQ employs several QA assessment tools designed to provide a better understanding of the components of the ADEQ Quality System and also to provide a basis for improving the ADEQ Quality Management System. "Internal" (programmatic) and "External" QA audits (ADEQ QA/QC Unit) are one of the principal tools for determining the effectiveness of the ADEQ QA/QC components. QA audit frequency and scheduling will vary with the type of review conducted. The following is a description of some of the evaluation tools:

9.2.1 Management System Reviews (MSRs)

An MSR is an independent assessment of a Program' s QA management practices and is generally performed by the ADEQ QA/QC Unit. MSRs address the effectiveness of management controls in achieving and assuring data quality; the adequacy of resources and personnel devoted to QA functions; the effectiveness of training and assessments; and, the applicability of data quality requirements. While MSRs can identify significant QA concerns and areas of needed improvement, they also point out noteworthy accomplishments.

ADEQ Program MSRs are generally conducted by an external party (typically the ADEQ QA/QC Unit) and focus on the Program's adherence to the approved Agency QMP and the

Quality Assurance Program Plans as well as the implementation of QA practices within a single program area. The ADEQ QA/QC Unit will attempt to conduct an MSR for every major Agency Program (including the Northern and Southern Regional Offices) once every three or four years. The ADEQ QA/QC Unit' s MSRs focus on the overall structure and procedures for accomplishing the QA program.

Most MSRs will examine the following elements:

An assessment of the overall effectiveness of the QA management system, as measured by its adherence to the approved QMP;
Procedures for developing Data Quality Objectives (DQOs);
Procedures for developing and approving QAPrPs and QAPjPs;
The effectiveness of existing QAPrP guidance and QAPjPs;
Procedures for developing and approving SOPs;
Procedures, criteria and schedules for conducting QA audits;
Tracking systems for assuring that the QA program is operating and that corrective actions disclosed by QA audits have been taken;
Responsibilities and authorities of various line managers and QA personnel for implementing the QA program;
The degree of management support; and,
The level of financial and other resources committed to implementing the QA program;

MSRs performed or arranged by the ADEQ QA/QC Unit will be conducted in accordance with the "***Guidance for the Management Systems Review Process***," EPA QA/G-3. The ADEQ may also make occasional use of independent, outside reviews of its quality assurance practices. When electing to use an outside source, the ADEQ QA/QC Program Supervisor, in consultation with the Division Director, will make arrangements for such a review by selecting an appropriate team of qualified reviewers (i.e., EPA Region IX). The goals and objectives of this type of review will be the same as if the assessment were conducted internally.

9.2.1.1 Review of ADEQ Quality Assurance Programs

The ADEQ QA/QC Unit will conduct internal assessments of the individual ADEQ Quality Assurance programs as described in the Agency QMP. All major data generating programs within the ADEQ will be reviewed every three to four years. These programs include, but are not limited to, Air Quality, Drinking Water, Superfund and RCRA Programs. These reviews will be authorized by the Director of the ADEQ and the results of the ADEQ QA/QC Unit evaluations will be transmitted to the ADEQ Division Director in a written memorandum from the ADEQ QA/QC Unit. The reviews are intended to accomplish the following objectives:

Identify any data quality problems;
Identify benchmark practices that could be used in other Agency programs;
Propose recommendations for resolving quality problems; and,

Confirm implementation and effectiveness of any recommended corrective actions.

The reviewed program will normally have 30 days to prepare a written response to the reviewer's memorandum. If the ADEQ QA/QC Unit recommended corrective actions, the reviewed program should address those recommendations and include a schedule for making any appropriate changes in its quality assurance procedures. These reviews will be used by the ADEQ Leadership team to gauge the effectiveness of the Agency QMP and of the programs' approaches to data quality management.

9.2.2 Technical Systems Audits (TSAs)

A Technical Systems Audit is conducted to assess the sampling and analytical quality control procedures used to generate environmental data. The ADEQ QA/QC Unit will use TSAs to evaluate laboratory and field procedures used by EPA, state personnel, and contractors. TSAs may entail a comprehensive, on-site evaluation of facilities; equipment calibration; personnel qualifications and training; record keeping procedures; and, data validation, data management and reporting of field and laboratory activities. Both laboratory and field TSAs are performed.

9.2.2.1 Laboratory TSAs

TSAs will be conducted on the Arizona Department of Health Services State Laboratory, ADEQ contract laboratories, and the contract laboratories of those consultants and contractors who submit analytical data to the ADEQ. TSAs will also be conducted on other Federal agency laboratories that perform sample analysis under Interagency Agreements with the ADEQ. The primary goals of TSAs will be to review the laboratory organization, operation, and capabilities; determine the reliability of data; and, note corrective action for any apparent deficiencies. Auditors for TSAs will be selected by the ADEQ QA/QC Program Supervisor based on their technical proficiency in the subject area. The designated auditors will be responsible for planning and conducting the audit, and reporting the findings to the laboratory manager and to the ADEQ QA/QC Program Supervisor.

9.2.2.2 Field TSAs

Oversight of field operations is an important part of the quality assurance process, and the ADEQ QA/QC Unit will conduct QA audits of field sampling activities, both for its own field operations, and on those contractors and other federal agencies that collect samples for programs sponsored by EPA. The Agency QMP will specify frequency and procedures for conducting field TSAs within specific program areas. The ADEQ QA/QC Program Supervisor will determine the adequacy of field TSAs when QAPjPs are reviewed, and also during any MSRs or other QA audits.

9.3 PERFORMANCE EVALUATIONS

Performance Evaluations (PEs) are conducted to assess the ability of a laboratory or field measurement system to obtain reliable data. PEs will normally be accomplished at laboratories

providing analytical services directly or indirectly for the ADEQ and will be traceable, whenever possible, through the National Institute of Standards and Technology (NIST). The evaluation consists of providing a reference, "blind" or "double blind" sample to the laboratory for analysis. This PE sample contains known concentrations of chemical constituents, or pollutants, of interest and will normally be in the appropriate media (e.g., soil, water, air). The analytical results obtained by the laboratory are compared to the known concentrations of the specific parameters contained in the PE sample(s) as a means of determining if the laboratory demonstrated its ability to properly identify and quantify pollutants within established or calculated control limits.

PE samples will be scheduled at a frequency specified by program requirements, or on an as-needed basis depending on the laboratory and program involved. Some national programs, such as the Public Water Supply Supervision (PWSS) and National Pollutant Discharge Elimination System (NPDES) programs, have regularly-scheduled PE studies in which participation is mandatory for designated laboratories. For the PWSS program, PE evaluations are required twice a year for all laboratories who wish to be certified for drinking water analysis. In addition, PE samples of specific parameters may be obtained from the appropriate EPA Office of Research Development laboratory or prepared commercially.

All PEs performed for the ADEQ, whether required on a regular basis or performed on a one time basis, will be coordinated through or requested from the ADEQ QA/QC Unit or designee. The results of PEs provide a means for assessing overall data integrity, and may be used as the criteria for selecting candidates for on-site evaluations.

9.4 DATA QUALITY EVALUATIONS

Data quality requirements and evaluation methods are addressed in the ADEQ QMP and also in specific QAPjPs. The QMP describes the methods by which data quality evaluations will be conducted and utilized and how these evaluations relate to the Data Quality Objectives.

9.4.1 Data Quality Assessments (DQAs)

A Data Quality Assessment (DQA) refers to the process used to determine whether the quality of a given data set is adequate for its intended use, using appropriate statistical tools. DQAs can be performed on all or selected projects involving data collection. The purpose of this type of evaluation is to determine whether the data collected are acceptable to the decision-maker or end user for their intended use, since the data are ultimately meaningful only in this context. A DQA involves a statistical comparison of the collected data with the Data Quality Objectives (DQOs) for the project. The intended use of the data are established by the project's Data Quality Objectives (see Chapter 7). This evaluation and comparison will result in the determination that the data are of known quality and that they either are useable or not useable for their intended purposes. Guidance for this procedure is provided in EPA QA/G-9, "***Guidance for Data Quality Assessment***," July, 1996.

The ADEQ QA/QC Unit routinely reviews and validates data generated by the ADHS

State Laboratory and by contract laboratories for the various Agency Programs. These data validation activities use checklists, standard operating procedures and standardized qualification codes to indicate data quality. The use of checklists and SOPs help standardize the data validation process and minimizes any discrepancy that may result between data validators within the ADEQ QA/QC Unit or between ADEQ and ADHS State Laboratory Personnel.

9.4.2 Data Quality Audits

A related evaluation tool involving data review and assessment is the data quality audit which is used to evaluate the documentation of the quality of data generated for a given project. This assessment primarily involves an evaluation of the completeness of the documentation of field and analytical procedures and quality control results; and usually involves tracing the paper trail accompanying the data from sample collection and custody to analytical results and entry into a data base. This technique is commonly used to verify the process involved in entering data residing in large regulatory data bases.

Results of both DQAs and data quality audits can be used in a number of ways. First, they can be used in making recommendations for changes in the design and performance of data collection efforts, and in the use and documentation of QC procedures. Secondly, they can be used as a guide for the planning and acquisition of supplemental data for the project and potentially for other related projects. Problems identified through DQAs may trigger the need for an MSR to determine management deficiencies, or a TSA to identify technical problems.

CHAPTER 10 QUALITY IMPROVEMENT

The ADEQ Leadership Team actively supports quality improvement by encouraging the ADEQ staff to:

Continually evaluate the effectiveness of current policies, procedures, and practices, and

Apply innovative approaches while maintaining integrity and accuracy

The above goals can be achieved in large by committing resources to the Agency' s Quality Management System to enable the constant evaluation of ADEQ programs, projects and individual staff performance. The ADEQ Quality Management System is designed to identify opportunities for improving the measurement process. Improvement can take the form of preventing quality problems from occurring by adjusting current work processes, or by seeking out better ways to do the work. The ADEQ Quality Assurance goal is to prevent quality problems from occurring or recurring.

Continual improvement is achieved by constant evaluation of program, project and individual performance in terms of ever changing environmental policies and objectives.

10.1 PROGRAM REVIEWS

It is the responsibility of line management for assuring staff participation for all program reviews and to review annually all QA activities of their staff, e.g., determining that SOPs are in place and revised if necessary, that QAPrPs are written and approved in advance of project start-up and that data quality assessments are made. All deviations and discrepancies noted during any independent or self-assessment review will be corrected promptly. Recommendations for modifications to the QMP, if necessary, will be forwarded in writing, to the ADEQ QA/QC Program Supervisor in a timely manner.

10.2 PROJECT REVIEWS

It is the responsibility of project managers to request project reviews and/or QA audits and to identify where improvements can be made. This process is started during the determination of data quality objectives and is finalized during the assessment of data quality. All corrective actions required during the life cycle of the project are to be filed in the official project file or with the project' s final report. Project managers are encouraged to utilize the services of the QA/QC Unit throughout the project to ensure that the requirements of the QMP are being met.

At a minimum, at the end of critical projects, an ADEQ team consisting of the Project Manager, a representative of the QA/QC Unit and other key project personnel will conduct an

evaluation of what worked and what areas need to be corrected or strengthened for future projects. The evaluation can include the findings resulting from scientific scrutiny (new technologies) or analytical measurements. The team will prepare a written report of their findings for Division Management and the Agency Leadership Team along with recommendations for improvement. The Leadership Team may choose to solicit other recommendations for improvement from persons not directly involved with the project. The ADEQ Leadership Team will decide which recommendations to implement in future projects.

LIST OF REFERENCES

EPA Order 5360.1, Policy and Program Requirements to Implement the Mandatory Quality Assurance Program, U.S. Environmental Protection Agency, April, 1984.

American National Standards Institute/American Society for Quality Control; ANSI/ASQC E-4 1994 Approved January 3, 1995.

EPA Requirements for Quality Management Plans (Draft Interim Final), EPA QA/R-2, U.S. EPA, Quality Assurance Management Staff, August, 1994.

Standard Operating Procedure for Quality Management Plan Reviews, QAD/96-1, U.S. EPA, Quality Assurance Division, January, 1996.

EPA Information Security Manual (Draft), U.S. EPA Office of Information and Resources Management, June, 1994.

U.S. EPA Acquisition Regulations, U.S. EPA Office of Administration and Resources Management.

EPA 1900 -- Contracts Management Manual, U.S. EPA Office of Administration, January 31, 1991.

U.S. EPA Grant Regulations, QA Requirements, 40 CFR Part 30.54 for Universities and Other Non-Profits, and 40 CFR Part 31.45 for States, tribal, and local governments.

Managing Your Financial Assistance Agreement, U.S. EPA Office of Administration and Resources Management, EPA 202-B-94-001, May, 1994.

Region III Order 5361.5, Location Identification Policy and Responsibilities, U.S. EPA Region III, Office of Policy & Management.

APPENDIX A

LIST OF ACRONYMS

A.A.C.	Arizona Administrative Code
ADEQ	Arizona Department of Environmental Quality
ADHS	Arizona Department of Health Services
AFIS	Arizona Financial Information System
AZURITE	Arizona Unified Repository For Informational Tracking of the Environment
A.R.S.	Arizona Revised Statute
BAFO	Best And Final Offer
CAA	Clean Air Act
CBI	Confidential Business Information
CDMG	Central Data Management Group
CERCLA	Comprehensive Environmental Response, Compensation and Liability Act
CFR	Code of Federal Regulations
CLP	Contract Laboratory Program
CWA	Clean Water Act
DQA	Data Quality Assessment
DQOs	Data Quality Objectives
EPA	Environmental Protection Agency
FSP	Field Sampling Plans
GITA	Government Information Technology Agency
IAGs	Inter-Agency Agreements
IOC	Inorganic Chemicals
IT	Information Technology
LTR	Licensing Time Frame
MSR	Management Systems Review
NIST	National Institute of Standards and Technology
NPDES	National Pollution Discharge Elimination System
OIT	Office of Information and Technology
ORD	Office of Research and Development
PE	Performance Evaluation
PWSS	Public Water Supply System
QA	Quality Assurance
QAD	Quality Assurance Division, EPA Office of Research and Development
QAPjP	Quality Assurance Project Plan
QAPrP	Quality Assurance Program Plan

LIST OF ACRONYMS (Continued)

QAMS	Quality Assurance Management Staff (Hq)
QC	Quality Control
QMP	Quality Management Plan
RCRA	Resource and Conservation Recovery Act
RPM	Remedial Project Manager
SAP	Sampling and Analysis Plans
SDWA	Safe Drinking Water Act
SLS	State Laboratory Services
SOC	Synthetic Organic Chemical
SOP	Standard Operating Procedure
TSA	Technical Systems Audit
TSCA	Toxic Substances Control Act
UST	Underground Storage Tank
VOC	Volatile Organic Chemical (or Compound)
WP	Water Pollution
WS	Water Supply

APPENDIX B

TERMS AND DEFINITIONS

Acceptable Quality Level - a limit above which quality is considered satisfactory and below which it is not. In sampling inspection, the maximum percentage of defects or failures that can be considered satisfactory as an average.

Accuracy - the degree of agreement between an observed value and an accepted reference value; a data quality indicator**.**

Activity - an all-inclusive term describing a specific set of operations or related tasks to be performed, either serially or in parallel (e.g., research and development, field sampling, analytical operations, equipment fabrication), that in total result in a product or service.

Assessment - the evaluation process used to measure the performance or effectiveness of a system and its elements. In this document, assessment is an all-inclusive term used to denote any of the following: audit, performance evaluation, management systems review, peer review, inspection or surveillance.

Audit - a planned and documented investigative evaluation of an item or process to determine the adequacy and effectiveness, as well as compliance with established procedures, instructions, drawings, quality assurance project plans, and other applicable documents.

Audit of Data Quality - a qualitative and quantitative evaluation of the documentation and procedures associated with environmental measurements to verify that the resulting data are of acceptable quality.

Bias - the systematic or persistent distortion of a measurement process which causes errors in one direction; a data quality indicator.

Characteristic - any property or attribute of a datum, item, process, or service that is distinct, describable, and measurable.

Comparability - the degree to which different methods, data sets and/or decision agree or can be represented as similar; a data quality indicator

Completeness - the amount of valid data obtained compared to the planned amount, and usually expressed as a percentage; a data quality indicator.

Computer Program - a sequence of instructions suitable for processing by a computer. Processing may include the use of an assembler, a compiler, an interpreter, or a translator to prepare the program for execution. A computer program may be stored on magnetic media, and be referred to as "software", or may be stored permanently on computer chips, and be referred to as "firmware". Computer programs covered by this document are those used for design analysis, data acquisition, data reduction, data storage (data bases), operation or control, and data base or document control registers when used as the controlled source of quality information.

Contractor - any organization or individual that contracts to furnish services or items or perform work.

Corrective Action - measures taken to rectify conditions adverse to quality and, where necessary, to preclude their recurrence.

Criteria - a standard on which judgement is based.

Customer - any individual or organization for whom items or services are furnished or work performed in response to defined requirements and expectations.

Data - facts or figures from which conclusions can be inferred.

Data Base - a collection of integrated data that can be used for a variety of applications.

Data of Known Quality - data are of known quality when the qualitative and quantitative components associated with their derivation are documented appropriately for their intended use and such documentation is verifiable and defensible.

Data Quality Assessment (DQA) - a process for performing statistical analysis to determine whether the quality of a data set is adequate for its intended use.

Data Quality Indicators - qualitative statistics and quantitative descriptors that are used to interpret the degree of acceptability or utility of data to the user. The principal data quality indicators are bias, precision, accuracy, comparability, completeness and representativeness.

Data Quality Objectives (DQOs) - qualitative and quantitative statements of the overall level of uncertainty that a decision-maker is willing to accept in results or decisions derived from environmental data. DQOs provide the statistical framework for planning and managing environmental data operations consistent with the data user's needs.

Data Usability - the process of ensuring or determining whether the quality of the data produced meets the intended use of the data.

Defensible - the ability to withstand any reasonable challenge related to the veracity of integrity of laboratory documents and derived data.

Design Review - a documented evaluation by a team, including personnel other than the original designers, the responsible designers, the customer for the work or product being designed, and a quality assurance representative to determine if a proposed design will meet the established design criteria and perform as expected when implemented.

Engineered Environmental Systems - an all-inclusive term used to describe pollution control devices and systems, waste treatment processes and storage facilities, and site remediation technologies and their components that may be utilized to remove pollutants or contaminants from the environment. Examples include wet scrubbers (air), soil washing (soil), granulated activated carbon unit (water), and filtration (air, water). Usually, this term will apply to hardware-based systems; however, it will also apply to methods or techniques used for pollutant reduction or containment of contamination to prevent further movement of the contaminants, such as capping, solidification or vitrification, and biological treatment.

Environmental Conditions - the description of a physical medium (e.g., air, water, soil, sediment) or biological system expressed in terms of its physical, chemical or biological characteristics.

Environmental Data - any information or measurements resulting from field data collection activity, laboratory analyses or modeling involving the assessment of chemical, physical or biological factors related to the environment, and that describe environmental processes or conditions, or the performance of engineered environmental systems.

Environmental Data Operations - work performed to obtain, use, or report information pertaining to environmental processes and conditions.

Environmental Monitoring - the process of measuring or collecting environmental data.

Environmental Processes - manufactured or natural processes that produce discharges to or impact the ambient environment.

Environmental Programs - generally considered a regulatory activity that results from the implementation of an act of Congress or other legislative body (e.g., a state). The duration of a program is usually legally seven years, (subject to renewal by the legislative body at various intervals), and is effectively continuous. Measurements are usually the same from year to year and take place on a recurring basis, e.g., quarterly monitoring for water or air pollutants, site assessments for Superfund, etc. Although the locations, parameters, and nature of measurements may change, the overall goal, which is to compare data to a regulatory standard, is generally constant. The Clean Water Act, Resource Conservation and Recovery Act, Clean Air Act, etc. are examples of programs, although not all data generation activities funded under these laws would necessarily be considered "program data" if they fall into the project category (see below). A program requires a QMP, describing its QA System, and usually a program QAPP (QA Program Plan) to describe in detail the process by which program data are obtained. In this document, an "environmental program" also refers to functional areas of work performed by groups or teams of people within the ADEQ organization.

Environmental Project - is defined as a data gathering activity that usually is of a finite length. Project data quality objectives are established during the planning phase and an assessment is made at the completion to determine whether the data quality objectives were met. Projects may include monitoring, but the data collected are frequently not intended for the use in enforcement of a regulatory standard. A trial burn, testing a new technology, a one-time ecosystem assessment and a habitat inventory are but a few examples of environmental projects. An environmental project requires a Quality Assurance Project Plan (QAPjP).

Environmentally Related Measurements - any measurement or information that describes environmental processes or conditions, or the performance of engineered environmental systems. Thus, environmental data include all chemical, physical, or biological measurements relating to the environment; however, it does not include demographic or financial data. In addition, environmental data includes both direct measurements of environmental conditions and data collected from other sources such as literature, industry surveys, computerized databases, historical data and mathematical models. Data from such sources are often called "secondary data."

External Oversight - a term used to convey related activities performed for EPA by the ADEQ; usually performed under contracts, grants or cooperative agreements. Used in reference to Quality Assurance Project Plans and the Quality Management Plan.

Financial Assistance - the process by which funds are provided by one organization (usually government) to another organization for the purpose of performing work or furnishing services or items. Financial assistance mechanisms include grants, cooperative agreements, and government interagency agreements.

Graded Approach - the process of basing the level of application of managerial controls applied to an item or work according to the intended use of results and the degree of confidence needed in the quality of the results.

Hazardous Waste - any waste materials that satisfies the definition of "hazardous waste" as given in 40 CFR Part 261, "Identification and Listing of Hazardous Waste".

Independent Assessment - an assessment performed by a qualified individual, group, or organization that is not a part of the organization directly performing and accountable for the work being assessed.

Inspection - an examination or measurement of an item or activity to verify conformance to specific requirements.

Internal Activities - a term used to describe the activities performed by ADEQ employees; usually used in relationship to Quality Assurance Project Plans, the QMP, contracts or grants.

Item - an all-inclusive term used in place of the following: appurtenance, facility, sample assembly, component, equipment, material, module, part, product, structure, subassembly,

subsystem, system, unit, documented concepts, or data.

Leadership Team - that group of ADEQ Management assembled and under the direction of the ADEQ Director. The Leadership Team consists of the following members: ADEQ Director; Deputy Director; Waste, Water, Air and Administrative Directors; Northern and Southern Regional Managers; Communications Officer; ADEQ Administrative Council and the General and Laboratory and General Services Manager.

Management - those individuals directly responsible and accountable for planning, implementing, and assessing work.

Management System - a structured non-technical system describing the policies, objectives, principles, organizational authority, responsibilities, accountability, and implementation plan of an organization for conducting work and producing items and services.

Management System Review (MSR) - the qualitative assessment of a data collection operation and/or organization(s) to establish whether the prevailing quality management structure, policies, practices, and procedures are adequate for ensuring that the type and quality of data needed are obtained.

Method - a body of procedures and techniques for performing an activity (e.g., sampling, chemical analysis, quantification) systematically presented in the order in which they are to be executed.

Mixed Waste - hazardous waste material, as defined by 40 CFR part 261 (RCRA), mixed with radioactive constituents.

Peer Review - a documented critical review of work characterized by the existence of potential uncertainty. The peer review is conducted by qualified individuals (or organization) who are independent of those who performed the work, but are collectively equivalent in technical expertise (i.e., peers) to those who performed the original work. The peer review is conducted to ensure that activities are technically adequate, competently performed, properly documented, and satisfy established technical and quality requirements. The peer review is an in-depth assessment of the assumptions, calculations, extrapolations, alternate interpretations, methodology, acceptance criteria, and conclusions pertaining to specific work and of the documentation that supports them. Peer reviews provide an evaluation of a subject where quantitative methods of analysis or measures of success are unavailable or undefined, such as in research and development.

Performance Evaluation Audit - a type of audit in which the quantitative data generated in a measurement system are obtained independently and compared with routinely obtained data to evaluate the proficiency of an analyst or laboratory.

Performance Evaluation Sample - **(PE)** a sample, the composition of which is unknown to the analyst and is provided to test whether the analyst/laboratory can produce analytical results within

the specified performance limits.

Procedure - a documented set of steps or actions that systematically specifies or describes how an activity is to be performed.

Process - an orderly system of actions that are intended to achieve a desired end or result. Examples of processes include analysis, design, data collection, operation, fabrication, and calculation.

Qualified Data - any data that have been reviewed and assessed as part of data validation, or data verification operations.

Quality - the sum of features and properties/characteristics of a process, item, or service that bears on its ability to meet the stated needs and expectations of the user.

Quality Assurance (QA) - an integrated system of management activities involving planning, implementation, assessment, reporting, and quality improvement to ensure that a process, item, or service is of the type and quality needed and expected by the customer.

Quality Assurance Division (QAD) - the EPA Headquarters office within the Office of Research and Development that establishes and promulgates Quality Assurance Policy for the Agency. Formerly the Quality Assurance Management Staff (QAMS).

Quality Assurance Project Plan (QAPjP) - a formal document describing in comprehensive detail the necessary QA, QC, and other managerial and technical activities that must be implemented to ensure that the results of the work performed will satisfy the stated performance (data quality) objectives.

Quality Control (QC) - the overall system of technical activities that measures the attributes and performance of a process, item, or service against defined standards to verify that they meet the stated requirements established by the customer.

Quality Improvement - a management program for improving the quality of operations. Such management programs generally entail a formal mechanism for encouraging worker recommendations with timely management evaluation and feedback or implementation.

Quality Management - that aspect of the overall management system of the organization that determines and implements the quality policy. Quality management includes strategic planning, allocation of resources, and other systematic activities (e.g., planning, implementation, and assessment) pertaining to the quality system.

Quality Management Plan (QMP) - a formal document that describes the quality system in terms of the organizational structure, functional responsibilities of management and staff, lines of authority, and required interfaces for those planning, implementing, and assessing all QA activities conducted.

Quality System - a structured and documented management system describing the policies, objectives, principles, organizational authority, responsibilities, accountability, and implementation plan of an organization for ensuring quality in its work processes, products (items), and services. The quality system provides the framework for planning, implementing, and assessing work performed by the organization and for carrying out required QA and QC procedures.

Readiness Review - a systematic, documented review of the readiness for the startup or continued use of a facility, process, or activity. Readiness reviews are typically conducted before proceeding beyond project milestones and prior to initiation of a major phase of work.

Remediation - the process of reducing the concentration of a contaminant (or contaminants) in air, water, or soil media to a level that poses an acceptable risk to human health.

Self-Assessment - an assessment of work conducted by individuals, groups, or organizations directly responsible for overseeing and/or performing the work.

Service - the category of economic activity that does not produce manufactured items. In environmental data operations or engineering projects, such activities include design, inspection, laboratory and/or field analysis, repair, and installation.

Significant Condition - any state, status, incident, or situation of an environmental process or condition of an engineered environmental system in which the work being performed will be adversely affected in a manner sufficiently serious to require corrective action to satisfy quality objectives or specifications and safety requirements.

Software Life Cycle - the period of time that starts when a software product is conceived and ends when the software product is no longer available for routine use. The software life cycle typically includes a requirements phase, a design phase, an implementation phase, a test phase, an installation and check-out phase, an operation and maintenance phase, and sometimes a retirement phase.

Standard Operating Procedure (SOP) - a written document that details the method for an operation, analysis, or action with thoroughly prescribed techniques and steps, and that is officially approved as the method for performing certain routine or repetitive tasks.

Supplier - any individual or organization furnishing items or services or performing work according to a procurement document or financial assistance agreement. This is an all-inclusive term used in place of any of the following: vendor, seller, contractor, subcontractor, fabricator, or consultant.

Surveillance - the act of monitoring or observing a process or activity to verify conformance to specified requirements.

Technical Review - a documented critical review of work that has been performed. The review is accomplished by one or more qualified reviewers who are independent of those who performed the work, but are collectively equivalent in technical expertise to those who performed the original work. The reviews are an in-depth analysis and evaluation of documents, activities, material, data, or items that require technical verification or validation for applicability, correctness, adequacy, completeness, and assurance that established requirements are satisfied.

Technical Systems Audit (TSA) - a thorough, systematic, on-site qualitative audit of facilities, equipment, personnel, training procedures, record keeping, data validation, data management, and reporting aspects of a system.

Validation - an activity that demonstrates or confirms that a process, item, data set, or service satisfies the requirements defined by the user.

Verification - the act of authenticating or formally asserting the truth that a process, item, data set, or service is, in fact, that which is claimed.

APPENDIX C

EPA ORDER 5360.1 CHG 1
07/16/98

POLICY AND PROGRAM REQUIREMENTS FOR THE MANDATORY AGENCY-WIDE QUALITY SYSTEM

1. PURPOSE. This Order re-affirms the policy defined by EPA Order 5360.1, April 1984, and expands that policy to accommodate the current and evolving needs of the Agency. The Order establishes policy and program requirements for the preparation and implementation of organizational or programmatic management systems pertaining to quality and contains the minimum requirements for the mandatory Agency-wide Quality System.

2. BASIS, AUTHORITY, AND REQUIREMENTS.

a. Since 1979, Agency policy has required participation in an Agency-wide Quality System by all EPA organizations (office, region, national center or laboratory) supporting environmental programs and by non-EPA organizations performing work in behalf of EPA through extramural agreements. This policy was affirmed in EPA Order 5360.1 in April 1984 and is reaffirmed in this Order.

b It is EPA policy that all environmental programs performed by EPA or directly for EPA through EPA-funded extramural agreements shall be supported by individual quality systems that comply fully with the American National Standard ANSI/ASQC E4-1994, *Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Program*s, incorporated herein by reference. ANSI/ASQC E4-1994 is a national consensus standard authorized by the American National Standards Institute (ANSI) and developed by the American Society for Quality Control (ASQC) that will provide a basis for the planning, implementation, documentation, and assessment of the Agency-wide Quality System. Adoption of this standard is consistent with the statutory authority of the *National Technology Transfer and Advancement Act of 1995* and the implementation authority of Office of Management and Budget (OMB) Circular A-119, *Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activitie*s.

b. Under Delegation of Authority-I-41, "Mandatory Quality Assurance Program," the Office of Research and Development (ORD) is the focal point in the Agency for Quality System policy. ORD is responsible for developing quality assurance and quality control (QA/QC) requirements and for overseeing implementation of the Agency-wide Quality System. The Assistant Administrator for Research and Development (AA/ORD) is designated as the Agency Senior Management Official for Quality. The Quality Assurance Division (QAD) is designated by the AA/ORD to serve as the central management authority for this program.

d. Each EPA Headquarters Office, National Program Office, Region, and components thereof, that conducts activities described by ANSI/ASQC E4-1994 shall develop and implement a quality system that complies with the requirements of this Order.

3. BACKGROUND.

a. The Agency-wide Quality System is a management system that provides the necessary elements to plan, implement, document, and assess the effectiveness of QA/QC activities applied to environmental programs conducted by or for EPA. This system embraces many functions including:

establishing quality management policies and guidelines for the development of organization- and project-specific quality plans;
establishing criteria and guidelines for planning, implementing, documenting, and assessing activities to obtain sufficient and adequate data quality;
providing an information focal point on QA/QC concepts and practices;
performing management and technical assessments to ascertain effectiveness of QA/QC implementation; and
identifying and developing training programs related to QA/QC implementation.

In addition, this Order expands the applicability of QA/QC to the design, construction, and operation by EPA organizations of environmental technology such as pollution control and abatement systems; treatment, storage, and disposal systems; and remediation systems.

b. A consistent, Agency-wide Quality System will provide, when implemented, the needed management and technical practices to assure that environmental data used to support Agency decisions are of adequate quality and usability for their intended purpose. Since most EPA decisions rest on environmental data, a management system is needed that provides for: (1) identification of environmental programs for which QA/QC is needed, (2) specification of the quality of the data required from environmental programs, and (3) provision of sufficient resources to assure that an adequate level of QA/QC is performed.

4. REFERENCES. The following documents contain provisions which, through reference in this text, constitute provisions of this Order. At the time of the issuance of this Order, the editions were valid. Since policy documents and standards are subject to periodic revision, users of this Order should apply the most recent editions of the documents indicated below.

a. 40 CFR Part 30, "Grants and Agreements With Institutions of Higher Education, Hospitals, and Other Non-Profit Organizations."

b. 40 CFR Part 31, "Uniform Administrative Requirements for Grants and Cooperative Agreement to State and Local Governments."

c. 40 CFR Part 35, "State and Local Assistance."

d. 48 CFR Chapter 15, Subpart 1546.2, "Contract Quality Requirements."

e. ANSI/ASQC E4-1994, *Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Program*s, American National Standard, January 1995.

f. Circular A-119, *Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activitie*s, Office of Management and Budget, February 1998.

g. Delegation of Authority I-41, "Mandatory Quality Assurance Program," U.S. Environmental Protection Agency, Washington, DC, April 1981.

h. *EPA Order 5360, EPA Quality Manual for Environmental Program*s, 1998.

i. *National Technology Transfer and Advancement Act of 199*5, PL104-113, March 1996.

5. SCOPE AND FIELD OF APPLICATION.

a. Scope. This Order defines the minimum requirements for quality systems supporting EPA environmental programs that encompass:

(1) the collection, evaluation, and use of environmental data by or for EPA, and
(2) the design, construction, and operation of environmental technology by EPA.

b. Applicability to Environmental Programs. This Order applies to (but is not limited to) the following environmental programs:

(1) the characterization of environmental or ecological systems and the health of human populations;

(2) the direct measurement of environmental conditions or releases, including sample collection, analysis, evaluation, and reporting of environmental data;

(3) the use of environmental data collected for other purposes or from other sources (also termed "secondary data"), including literature, industry surveys, compilations from computerized data bases and information systems, results from computerized or mathematical models of environmental processes and conditions; and

(4) the collection and use of environmental data pertaining to the occupational health and safety of personnel in EPA facilities (e.g., indoor air quality measurements) and in the field (e.g., chemical dosimetry, radiation dosimetry).

a. Applicability to Other EPA Programs. This order applies to the collection and use of medical testing data from Government and non-Government personnel in EPA facilities for determination of substance abuse.

d. Organizational Applicability.

(1) EPA Organizations. The Agency-wide Quality System requirements defined by this Order apply to all EPA organizations, and components thereof, in which the environmental programs conducted involve the scope of activities described in Section 5.a above. The authority of this Order applies only to EPA organizations except as addressed by Section 5.d(2) below.

(2) Extramural Agreements. Agency-wide Quality System requirements may also apply to non-EPA organizations. These requirements are defined in the applicable regulations governing extramural agreements. Agency-wide Quality System requirements may also be invoked as part of negotiated agreements such as memoranda of understanding. Non-EPA organizations that may be subject to quality system requirements include:

(a) Any organization or individual under direct contract to EPA to furnish services or items or perform work (i.e., a contractor) under the authority of 48 CFR Chapter 15, Part 1546, (including applicable work assignments, delivery orders, and task orders);

(b) Institutions of higher education, hospitals, and other non-profit recipients of financial assistance (e.g., Grants and Cooperative Agreements) under the authority of 40 CFR Part 30;

(c) State, local, and Tribal governments receiving financial assistance under the authority of 40 CFR Part 31 and 35; and

(d) Other Government Agencies receiving assistance from EPA through interagency agreements.

6. QUALITY SYSTEM REQUIREMENTS AND IMPLEMENTATION.

a. Quality System Requirements. EPA organizations covered by the scope of this Order shall develop, implement, and maintain a quality system that demonstrates conformance to the minimum specifications of ANSI/ASQC E4-1994 and that additionally provides for the following:

(1) A quality assurance manager (QAM), or person assigned to an equivalent position, who functions independently of direct environmental data generation, model development, or technology development responsibility; who reports on quality issues to the senior manager having executive leadership authority for the organization; and who has sufficient technical and management expertise and authority to conduct independent oversight of and assure the implementation of the organization' s quality system in the environmental programs of the organization.

(2) A Quality Management Plan (QMP), which documents the organization' s quality policy, describes its quality system, identifies the environmental programs to which the quality system applies, and which is implemented following approval by the organization' s executive leadership and the AA/ORD.

(3) Sufficient resources to implement the quality system defined in the approved QMP.

(4) Assessments of the effectiveness of the quality system at least annually.

(5) Submittal to the AA/ORD of the Quality Assurance Annual Report and Work Plan (QAARWP) for the organization that summarizes the previous year' s QA/QC activities and outlines the work proposed for the current year.

(6) Use of a systematic planning approach to develop acceptance or performance criteria for all work covered by this Order. (See Section 3.3.8 of the EPA Quality Manual for Environmental Programs, 1998.)

(7) Approved Quality Assurance Project Plans (QAPPs), or equivalent documents defined by the QMP, for all applicable projects and tasks involving environmental data with review and approval having been made by the EPA QAM (or authorized representative defined in the QMP). QAPPs must be approved prior to any data gathering work or use, except under circumstances requiring immediate action to protect human health and the environment or operations conducted under police powers.

(8) Assessment of existing data, when used to support Agency decisions or other secondary purposes, to verify that they are of sufficient quantity and adequate quality for their intended use.

(9) Implementation of Agency-wide Quality System requirements in all applicable EPA-funded extramural agreements (see Section 5.d(2)).

(10) Implementation of corrective actions based on assessment results.

(11) Appropriate training, for all levels of management and staff, to assure that QA/QC responsibilities and requirements are understood at every stage of project implementation.

b. Quality System Implementation.

(1) EPA Organizations. Mandatory requirements for implementing this Order are contained in the *EPA Quality Manual for Environmental Programs*, hereafter referred to as the *EPA Quality Manual*. Additional non-mandatory guidance for implementing the requirements are provided in EPA Guidance Documents which may be applied to intramural environmental programs, as appropriate.

(2) Extramural Agreements.

(a) Mandatory requirements for implementing this Order are defined in applicable EPA regulations. EPA Requirements Documents provide specifications for satisfying the requirements of these regulations. The EPA Requirements Documents provide the equivalent information to the *EPA Quality Manual*, except they have been written especially for the extramural user. Non-mandatory guidance for implementing the requirements are provided in EPA Guidance Documents which may be applied to extramural environmental programs, as appropriate.

(b) Extramural organizations that provide objective evidence (such as a QMP or quality manual) of conforming to the specifications of the American National Standard ANSI/ASQC E4-1994 are in compliance with this Order.

7. GENERAL REQUIREMENTS FOR MANAGERS AND STAFF.

a. Assistant Administrator for Research and Development and ORD Senior Managers.

(1). The AA/ORD, as the Agency Senior Management Official for Quality, shall:

(a) Establish, document, and periodically revise Agency policies and procedures for planning, implementing, and assessing the effectiveness of the mandatory, Agency-wide Quality System.

(b) Review and approve QMPs from Agency components conducting environmental programs for implementation for up to five years.

(c) Perform periodic management assessments of all EPA organizations conducting environmental programs to determine the effectiveness of their mandatory quality systems and recommend corrective actions.

(d) Develop generic training programs, for all levels of EPA management and staff, so that quality management responsibilities and requirements are understood at every stage of project implementation.

(2) The AA/ORD and ORD senior managers shall:

(a) Designate a representative for quality management and QA/QC to advise and assist the AA in the planning, implementation, documentation, and assessment of the quality systems for organizations under the AA's responsibility.

(b) Ensure that all ORD components and applicable programs comply fully with the requirements of this Order.

(c) Ensure that quality management is an identified activity with associated resources adequate to accomplish its program goals and is implemented as prescribed in approved QMPs.

(d) Ensure that all ORD-funded environmental programs implemented through extramural agreements comply fully with applicable QA/QC requirements.

(e) Ensure that environmental data from research and development programs are of sufficient quantity and adequate quality for their intended use and are used consistent with such intentions.

(f) Perform periodic assessments of ORD organizations conducting environmental programs to determine the conformance of their mandatory quality systems to their approved QMPs and the effectiveness of their implementation.

(g) Ensure that deficiencies highlighted in the assessments of ORD organizations are appropriately addressed.

(h) Identify program-specific QA/QC training needs for all levels of management and staff and provide for this training.

(i) Ensure that performance plans for supervisors, senior managers, and appropriate staff contain critical element(s) that are commensurate with the quality management responsibilities assigned by this Order and the organization' s QMP.

b. National Program Office Assistant Administrators and Senior Managers.

(1) Each National Program Office (NPO) Assistant Administrator shall designate a representative for quality management and QA/QC to advise and assist the AA in the planning, implementation, documentation, and assessment of the quality systems for organizations under the AA's responsibility.

(2) The National Program Office (NPO) Assistant Administrators and senior managers shall:

(a) Ensure that all NPO components and applicable programs comply fully with the requirements of this Order.

(b) Ensure that quality management is an identified activity with associated resources adequate to accomplish its program goals and is implemented as prescribed in the organization's approved QMP.

(c) Ensure that all environmental programs implemented through extramural agreements comply fully with applicable QA/QC requirements.

(d) Ensure that environmental data from the parts of National Programs implemented by the Regions or delegated to State, local, and Tribal governments are of sufficient quantity and adequate quality for their intended use and are used consistent with such intentions.

(e) Ensure that all proposed and final regulations needing environmental data during their development or implementation include the application of sufficient and adequate QA/QC during the collection and use of such data.

(f) Perform periodic assessments of NPO organizations conducting environmental programs to determine the conformance of their mandatory quality systems to their approved QMPs and the effectiveness of their implementation.

(g) Ensure that deficiencies highlighted in the assessments are appropriately addressed.

(h) Identify program-specific QA/QC training needs for all levels of management and staff and provide for this training.

(i) Ensure that performance plans for supervisors, senior managers, and appropriate staff contain critical element(s) that are commensurate with the quality management responsibilities assigned by this Order and the organization' s QMP.

c. Regional Administrators and Senior Managers. Regional Administrators and senior managers shall:

(1) Ensure that all Regional components and programs comply fully with the requirements of this Order.

(2) Ensure that quality management is an identified activity with associated resources adequate to accomplish its program goals and is implemented as prescribed in the organization's approved QMP.

(3) Ensure that all environmental programs implemented through extramural agreements comply fully with applicable QA/QC requirements.

(4) Ensure that the environmental data from environmental programs delegated to State, local, and Tribal governments are of sufficient quantity and adequate quality for their intended use and are used consistent with such intentions.

(5) Ensure that training is available for State, local, and Tribal governments performing environmental programs for EPA in the fundamental concepts and practices of quality management and QA/QC that they may be expected by EPA to perform.

(6) Perform periodic assessments of Regional organizations conducting environmental programs to determine the conformance of their mandatory quality systems to their approved QMPs and the effectiveness of their implementation.

(7) Ensure that deficiencies highlighted in the assessments are appropriately addressed.

(8) Identify QA/QC training needs for all levels of management and staff and provide for this training.

(9) Ensure that performance plans for supervisors, senior managers, and appropriate staff contain critical element(s) that are commensurate with the quality management responsibilities assigned by this Order and the organization' s QMP.

d. Quality Management Personnel. Quality management personnel, including the QAM, refers to individuals within the organization who are assigned specific quality management duties and are delegated authority for quality management as defined in the organization's QMP. The functions of the quality management personnel may be totally related to quality system activities or be in conjunction with other functions and responsibilities within the organization. If these personnel have other functions to perform, there should be no conflict of interest. Specific duties and responsibilities of all quality management personnel shall be documented in the organization's QMP. Specific responsibilities shall include:

(1) facilitating QMP development and approval by the organization and preparing updates to the approved QMP;

(2) representing the organization to QAD and other groups on matters pertaining to quality management and QA/QC;

(3) providing expert assistance to the staff in the organization on QA/QC policies, requirements, and procedures applicable to procurement and technical activities;

(4) reviewing and approving QMPs and QAPPs submitted by intramural programs and by holders of extramural agreements as defined in the organization' s QMP;

(5) identifying QA/QC training needs for the organization;

(6) providing oversight of QA/QC implementation in the environmental programs conducted by or for the organization; and

(7) performing assessments of environmental programs and confirming the effectiveness of corrective actions.

e. Agency Managers and Staff.

(1) Managers at all levels shall:

(a) Ensure that quality management is an identified activity with associated resources adequate to accomplish its program quality goals.

(b) Ensure that all organizational components and programs comply fully with the requirements of this Order.

(c) Ensure that all applicable environmental programs for which management is responsible comply fully with the requirements of this Order.

(d) Perform all other quality management roles and responsibilities assigned to them in their organization' s QMPs.

(2) Managers and staff shall:

(a) Ensure that all applicable intramural programs and activities comply fully with the requirements of this Order.

(b) Ensure that all applicable extramural environmental programs for which the manager or staff member is responsible comply fully with the requirements of this Order.

(c) Assure that the results of environmental programs are of sufficient quantity and adequate quality for their intended use.

(d) Perform all other quality management roles and responsibilities assigned to them in their organization' s QMPs.

8. DEFINITIONS. The following terms have special meanings in relation to this Order.

a ***assessment*** - the evaluation process used to measure the performance or effectiveness of a system and its elements. As used here, assessment is an all-inclusive term used to denote any of the following: audit, performance evaluation, management review, peer review, inspection, or surveillance.

b. ***environmental data*** - any measurements or information that describe environmental processes, location, or conditions; ecological or health effects and consequences; or the EPA ORDER 5360.1 CHG 1 07/16/98 performance of environmental technology. For EPA, environmental data include information collected directly from measurements, produced from models, and compiled from other sources such as data bases or the literature.

c **environmental programs** - work or activities involving the environment, including but not limited to: characterization of environmental processes and conditions; environmental monitoring; environmental research and development; the design, construction, and operation of environmental technologies; and laboratory operations on environmental samples.

d. **environmental technology** - an all-inclusive term used to describe pollution control devices and systems, waste treatment processes and storage facilities, and site remediation technologies and their components that may be utilized to remove pollutants or contaminants from or prevent them from entering the environment. Examples include wet scrubbers (air), soil washing (soil), granulated activated carbon unit (water), and filtration (air, water). Usually, this term applies to hardware-based systems; however, it also applies to methods or techniques used for pollution prevention, pollutant reduction, or containment of contamination to prevent further movement of the contaminants, such as capping, solidification or vitrification, and biological treatment

e. **extramural agreement** - a legal agreement between EPA and an organization outside EPA for items or services to be provided. Such agreements include contracts, work assignments, delivery orders, task orders, cooperative agreements, research grants, state and local grants, and EPA-funded interagency agreements.

f. **management system** - a structured non-technical system describing the policies, objectives, principles, organizational authority, responsibilities, accountability, and implementation plan of an organization for conducting work and producing items and services.

g. **organization** - a company, corporation, firm, enterprise, or institution, or part thereof, whether incorporated or not, public or private, that has its own functions and administration. In the context of this Order, an EPA organization is an office, region, national center or laboratory.

h. **process** - a set of interrelated resources and activities which transforms inputs into outputs. Examples of processes include analysis, design, data collection, operation, fabrication, and calculation.

i. **quality** - the totality of features and characteristics of a product or service that bear on its ability to meet the stated or implied needs and expectations of the user.

j. **quality assurance (QA)** - an integrated system of management activities involving planning, implementation, documentation, assessment, reporting, and quality improvement to ensure that a process, item, or service is of the type and quality needed and expected by the customer.

k. **quality assurance manager (QAM)** - the individual designated as the principal manager within the organization having management oversight and responsibilities for planning, documenting, coordinating, and assessing the effectiveness of the quality system for the organization.

l. **quality assurance project plan (QAPP)** - a document describing in comprehensive detail the necessary QA/QC and other technical activities that must be implemented to ensure that the results of the work performed will satisfy the stated performance criteria.

m. **quality control (QC)** - the overall system of technical activities that measures the attributes and performance of a process, item, or service against defined standards to verify that they meet the stated requirements established by the customer; operational techniques and activities that are used to fulfill requirements for quality.

n. **quality management** - that aspect of the overall management system of the organization that determines and implements the quality policy. Quality management includes strategic planning, allocation of resources, and other systematic activities (e.g., planning, implementation, documentation, and assessment) pertaining to the quality system.

o. **quality management plan (QMP)** - a document that describes a quality system in terms of the organizational structure, policy and procedures, functional responsibilities of management and staff, lines of authority, and required interfaces for those planning, implementing, documenting, and assessing all activities conducted.

p. **quality system** - a structured and documented management system describing the policies, objectives, principles, organizational authority, responsibilities, accountability, and implementation plan of an organization for ensuring quality in its work processes, products (items), and services. The quality system provides the framework for planning, implementing, documenting, and assessing work performed by the organization and for carrying out required QA/QC.

q. **user** - an organization, group, or individual that utilizes the results or products from environmental programs or the customer for whom the results or products were collected or created.

9. SUPERSESSION. This Order replaces EPA Order 5360.1, dated April 1984, in its entirety.

/s/
David J. O'Connor
Director
Office of Human Resources
and Organizational Services

APPENDIX D

0033.001 **PUBLIC ACCESS TO PUBLIC RECORDS POLICY**

Level One **Arizona Department of Environmental Quality**

Originator: Mark Santana, Administrative Counsel
Office of Administrative Counsel

Contact for Information: Mark Santana

Issue Date: May 26, 1995 **Amended:** May 1, 1998

PURPOSE

The purpose of the Public Records Policy is to provide guidance to ADEQ on how to respond to requests for disclosure of public records. This policy is intended to comply with the Arizona's Public Records Law, A.R.S. § 39-121 et seq., confidentiality statutes found in Title 49 of the Arizona Revised Statutes (§§ 49-205(A)(1) 432, 928(A)(1), 967, and 1012) and mandatory disclosure statutes (§§ 49-205(B), 49-432(E), 49-487(D), 49-928(C), and 49-967(C)). This policy recognizes that the public has a right of access to public records based on law that should be addressed in a manner consistent with the department's customer focus values. The policy also recognizes that there are legitimate reasons based in law for not disclosing certain records and that public access to records must occur in an orderly manner that assures the security of the records.

POLICY

The general policy of the department with respect to public records is one of open disclosure. All public records that are not confidential shall be made available to the public for inspection and copying during normal business hours (A.R.S. § 39-121 et seq.,§§ 49-205(B), 49-432(E), 49-487(D), 49-928(C), and 49-967(C)). To determine whether a record is confidential see Identification and Protection of Confidential Records Policy #0032.000. Public records are defined as all records reasonably necessary or appropriate to maintain an accurate knowledge of the official activities of the department. Public records include all documents and information in any media format, including written or electronic according to A.R.S. §41-1350. Public records may be of the following types:

1. books,
2. papers,
3. maps,
4. videos,
5. photographs,
6. computer printouts,
7. correspondence,
8. tape recordings,
9. floppy disks,

10. microfilms and other documents or materials regardless of physical form or character.
11. electronic mail
12. daily planner or other record books supplied by ADEQ.

Public records made or received by the department in connection with the transaction of public business which demonstrate evidence of the organization, functions, policies, decisions, procedures, operations or activities of the department are considered public records. Library materials made or acquired solely for reference purposes, extra copies of documents preserved for convenience of reference, and stocks of publications intended for sale or distribution to interested persons are not included within the definition of public records.

Draft documents including electronic and marked up copy drafts are not public documents. The circumstances where electronic mail constitutes a public document is addressed in ADEQ's electronic mail policy (Policy # 0000.000).

RESPONSIBILITY
Supervisors are responsible to ensure that this policy and its procedures are followed by all employees under their supervision.

APPLICABILITY
The policy applies to all agency employees.

PROCEDURES
1. All requests by the public to inspect public records should be made in writing before the ADEQ staff provides the documents. The request form may be filled out by the requester or ADEQ staff. If the requestor declines to fill out a form, the staff shall provide them with the documents and fill out the form for them.

   Written requests for disclosure of public records should reasonably describe the records sought in order to permit their identification and location within the department. The request may be made on the form in Exhibit #1, the Public Records Review/Copy Request Form. The PRRCR form should be maintained in a file by the division or regional office where the requests are submitted.

2. ADEQ staff should provide requested documents and copies to the public as soon as possible after the request is made. If the ADEQ staff cannot provide the documents at the time requested by the reviewer, then a mutually agreed-upon time may be established with the requester.

3. ADEQ staff shall make reasonable efforts to assist the public with identification and description of public records sought and with explaining the documents once disclosed.

4. When a request is denied, ADEQ staff shall inform the requester in writing of all the following:

A. A description of the records withheld,

B The basis for withholding the records,

C. The appeal process as follows:

1. A person who has been denied access to public records may appeal that determination to the Office of Administrative Counsel by letter.

2. The Administrative Counsel (who may consult with the Attorney General) shall review the request and make a final determination in writing on whether the information should be disclosed or be given confidential treatment.

5. Review of public records should be done in an area that can be supervised by the ADEQ staff who provides the public record, or in another manner that ensures the documents are secure at all times.

6. Except in unusual circumstances, briefcases and boxes that belong to the requester shall be left in the reception area away from the area where the public record is reviewed.

7. Items allowed in the area where the public record is reviewed (except for the public record) are generally limited to writing instruments, a notepad, a computer, post-its or paper clips to mark items for copying.

8. If the public requests copies of the documents, the ADEQ Photocopy Policy 0027.000 shall be complied with for costs and delivery services.

9. In all transactions with any member of the public requesting access to public records, ADEQ staff shall respond in a manner that respects the public's legal right to access and that is consistent with the department's customer service focus.

APPROVED BY:
For Historical document, see Policy #0033.000. (Place cursor on the inverted triangle and press enter to see this document.)

EXHIBIT #1:

ADEQ PUBLIC RECORDS REVIEW/COPY REQUEST FORM

(Side #1 of 2)

REQUESTER TO COMPLETE THIS SIDE OF PAGE:

Date of Request:_____

Print Name of Requester:

Signature of Requester:_____

Mailing Address:_____

City:_____State:_____Zip Code:_____

Telephone Number:_____

REQUEST TO: (Place "X" on appropriate line below)

1. Only Review or Inspect Public Records _____
2. Review/Inspect Public Records, and Copies Made _____
3. Only Have Public Records Copied _____

RECORDS REQUESTED TO BE INSPECTED, REVIEWED, OR COPIED:

(Mark pages or items to be copied with "paper clips" or "post-it notes", and return to ADEQ Unit/Office for completing your request.)

_____
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THIS SIDE TO BE COMPLETED BY ADEQ --- (Side #2 of 2):

RECEIVING REQUEST:

1. ADEQ Unit/Office _____

2. ADEQ Staff Receiving Request _____

HANDLING REQUEST:

1. ADEQ Unit/Office _____

2. ADEQ Staff Handling Request _____

ARE COPYING/REPRODUCTION PAYMENTS REQUIRED BEFORE PUBLIC RECORDS PROVIDED?

1. YES _____

DOES REQUESTER PROVIDE "ADEQ PAYMENT RECEIPT" IN ORDER FOR COPYING TO BE INITIATED BY ADEQ OR ITS VENDOR?

1. NO _____(ADEQ member must direct requester to ADEQ Accounting "Cashier" to make payments, and receive ADEQ Payment Receipt before any copies can be made.)

2. YES _____(ADEQ member can make copies and give to requester.)

DATE REQUEST COMPLETED OR CLOSED: _____

COMPLETING REQUEST:

1. ADEQ Unit/Office _____

2. ADEQ Staff Completing Request _____

IF ACCESS TO REQUESTED RECORDS IS DENIED; DESCRIBE THE RECORD WITHHELD, THE BASIS FOR WITHHOLDING, AND PROVIDE A COPY OF THE APPEAL PROCESS FOUND IN PROCEDURE 4.C.

_____
_____
_____
_____
_____

APPENDIX E

0032.001 **CONFIDENTIAL RECORDS POLICY**

Level One **Arizona Department of Environmental Quality**

Originator: Mark Santana, Administrative Counsel
Office of Administrative Counsel

Contact for Information: Mark Santana

Issue Date: May 26, 1995 **Amended:** May 1, 1998

PURPOSE
The purpose of the Confidential Records Policy is to ensure confidential records are properly identified and not made available to the public. There is a strong presumption that all records are available for public review. A limited group of records, identified in this policy, may be withheld as confidential.

POLICY
Public records are defined in policy #0033.001. Whenever an ADEQ employee removes a public record from a facility file, the employee should check for confidential records and separate them to ensure the records are not disclosed. A confidential record shall be marked "confidential." Except as provided in paragraph 9 for claimed confidential information, every employee may assume the records identified in the "Procedures" are confidential and not disclose them to the public except for the information described in A.R.S. § § 49-205(B), 49-432(E), and 49-967(C). A decision to withhold confidential documents should not be made without the approval of the employee's section manager or OAC. If any employee is uncertain whether a record is confidential, the employee may consult with the Office of Administrative Counsel (OAC).

The following documents shall be considered confidential and may be withheld from public review under the following circumstances:

1. "Confidential by Statute" records including: records which may divulge trade secrets or certain financial information. In addition, documents relating to a criminal investigation or an ongoing civil enforcement action may be privileged. (See section B1. "Records Made Confidential by Statute" in the Guidelines and Procedures for Identification and Protection of Confidential Records Policy.)

2. "Executive Privilege" records: written communications sent to the director concerning ADEQ policy or administrative enforcement decisions (See section B3. "Evidentiary Privileges" in the Guidelines and Procedures for Identification and Protection of Confidential Records Policy).

3. "Attorney-Client Privilege" records include:

   a. Written communications between ADEQ and the Attorney General's Office or a document concerning legal advice provided by the Attorney General;

   b. Legal advice given by the administrative counsel to the ADEQ director, deputy director or a division director, deputy assistant director, regional office manager or an employee directed by a management team as listed above to seek OAC advice.

   (See section B3. "Evidentiary Privileges" in the Guidelines and Procedures for Identification and Protection of Confidential Records Policy.)

4. "Records Sealed by Court Order": Any record that has been sealed by order of a court. The court order will be attached to the document.

5. "Investigative Privilege": Any records, reports or information gathered in the course of an ongoing or contemplated civil or criminal enforcement action, which if disclosed, could compromise the investigation or impending prosecution. (See section B1. "Records Made Confidential by Statute" in the Guidelines and Procedures for Identification and Protection of Confidential Records Policy.)

6. "Informant's Privilege": The disclosure of the identity of any person who furnishes information to law enforcement personnel concerning violations in furtherance of the public interest in law enforcement. (See section B2. "Informant's Privilege" in the Guidelines and Procedures for Identification and Protection of Confidential Records Policy.)

7. "Privacy Privilege" records: A document does not have to be disclosed if it would be offensive to the personal privacy interests of a reasonable person and is not of legitimate concern to the public. (See section B4. "Invasion of Privacy" in the Guidelines and Procedures for Identification and Protection of Confidential Records Policy.)

8. "Best Interest of the State Privilege" records: A document which, if disclosed, would seriously interfere with ADEQ's performance of its duties. (See B6. "Best Interest of the State" in the Guidelines and Procedures for Identification and Protection of Confidential Records Policy.)

9. "Claimed Confidential" records include information submitted to ADEQ pursuant to ADEQ's request or demand, and which a person has marked "confidential" should not be provided without the written permission of OAC. (See section M. "Procedure for Confidential Public Records Submitted to ADEQ" in the Guidelines and Procedures for Identification and Protection of Confidential Records Policy.) If an employee finds a record which is either stamped or presumed to be confidential, the employee **may** request a timely review by the OAC. If for any reason the OAC is not immediately available, the employee **may** request a determination be made about the confidentiality of the record by an immediate supervisor or manager who is covering the supervisor's duties.

RESPONSIBILITY
The Office of Administrative Counsel has primary responsibility for ensuring that this policy is implemented and followed throughout the agency. Supervisors are responsible for ensuring that this policy and its procedures and guidelines are followed by employees under their supervision.

APPLICABILITY
This policy applies to all agency employees.

PROCEDURES
1. Requests for confidential records should conform to the requirements of the Public Access to Records Policy, #0033.001.

2. When an employee handles a file or document that is requested for review by the public, the employee should review the file and check for documents that are marked or should be marked confidential. If an employee is in doubt about the confidentiality of a document, the employee may, with the approval of the section or regional office manager or OAC, presume the document is confidential and withhold it pending a decision on confidentiality. The employee may review the document with an OAC attorney. If an OAC attorney is not available, an assistant attorney general may be consulted.

3. Whenever ADEQ makes a written request or demand that a person furnish information which is likely to be regarded by the person as entitled to confidential treatment, or whenever ADEQ prescribes a form for use by persons in furnishing information to ADEQ, the request, demand or form shall include a notice which states that the person may assert a claim of confidentiality covering all or part of the information pursuant to the appropriate statute. [See Subsection F. of the Guidelines For Identification and Protection of Confidential Records Policy for further information.] The notice shall state that if the person does not assert a claim of confidentiality along with the information when it is received by ADEQ, the information may be made available to the public without further notice.

4. Claims of confidentiality may be asserted on forms available from ADEQ or by placing on or attaching to the information at the time it is submitted to ADEQ, a cover letter or notice identifying that all or part of the information is entitled to confidential treatment. Allegedly confidential portions of otherwise non-confidential documents should be clearly identified.

5. The unit, section or regional office manager, may consult with the Office of Administrative Counsel in making the initial determination of whether information submitted to ADEQ under a claim of confidentiality should be designated as confidential.

    a. In making this determination, the unit manager, section manager or regional office manager should consider whether the information is required to be kept confidential by statute See section B1. "Records Made Confidential by Statute." The person making the initial determination should also consider any relevant class determinations (See class determinations below). If no statute or class determination of confidentially requires that the record be given confidential treatment, the unit manager, section manager, or office manager may consider whether ADEQ should exercise its

discretionary power to designate the information as confidential. The unit manager, section manager, or office manager may also consider whether the disclosure of the information would be an unwarranted invasion of privacy, whether any privilege prevents disclosure, or whether maintaining the confidentiality of the information is in the best interest of the state [See sections B2, B3, and B4 of the "Procedures."]

b. The unit manager, section manager, or office manager may contact the person asserting the claim of confidentiality and request more information on whether the claimant has taken measures to prevent disclosure of the information in question, whether the information has been disclosed already to others and whether any precautions have been taken to prevent disclosure. If it appears that the person making the claim of confidentiality has taken no measures to prevent disclosure of the information or that the information is reasonably obtainable without the consent of the person making the claim of confidentiality, then the unit manager or section manager may deny the claim.

6. Class determinations: The section/office manager may issue a class determination of confidentiality if [s]he finds that ADEQ possesses or is obtaining related items of information that have common characteristics. If the section/office manager finds that these common characteristics will necessarily result in the identical treatment of all the related items, [s]he may issue a class determination that the class of public records are or are not confidential. For example, the aquifer protection application section manager, who is responsible for maintaining aquifer protection permit applications, may determine that all financial information contained in such applications is confidential and make a class determination to guide the APP unit staff. In making such determinations, the section/office manager may consult with the Office of the Administrative Counsel.

7. Where a request for public documents is denied, ADEQ staff shall follow the procedures set forth in the Public Access to Public Records Policy [Subsection 4] in issuing the denial.

8. A denial of claimed confidentiality or a refusal to disclose a confidential record may be appealed as follows:

a. A person who has been denied access to public records or whose claim of confidentiality has been denied may appeal that determination to the Office of Administrative Counsel by letter.

b. The Administrative Counsel (who may consult the Attorney General) shall review the request and make a final determination in writing on whether the information should be disclosed or be given confidential treatment.

DOCUMENT REVIEW GUIDELINES

The following guidelines should be used by ADEQ staff in implementing the Confidential Records Policy.

A. Access to public records

"Public record" is described in the Public Access to Public Records Policy #0033.001.

Department staff should keep in mind the general policy favoring disclosure of public records. (See Public Access to Public Records Policy #00033.001.) Any refusal to disclose public records must be supported by a rationale that is consistent with the basis for nondisclosure outlined in the Confidential Records Policy, Procedures and Guidelines.

B. Confidential Records

1. Public records made confidential by statute.

The legislature has declared that certain public records are confidential and may not be disclosed.

a. Water Quality Control

A.R.S. § 49-205(A)(1):

This statute allows department staff to designate any records, reports or information obtained from any person under Chapter 2 of Title 49 as confidential if the information contains "trade secrets."

A.R.S. § 49-205(A)(2):

This statute permits the attorney general to designate certain documents related to criminal investigations or civil actions as confidential if the disclosure would be detrimental to an ongoing criminal investigation or to an ongoing or contemplated civil enforcement action in Superior Court.

Notwithstanding the confidentiality provisions cited above, the director may disclose any records, reports or information obtained from any person under the Water Quality Control chapter, including records, reports or information obtained by the director or ADEQ employees to other state employees concerned with the administration of the Water Quality Control chapter or if the records, reports or information are relevant to any administrative or judicial proceeding under the Water Quality Control chapter [See A.R.S. § 49-205(C)(1)]. The director or ADEQ employees also may disclose such information to employees of the United States Environmental Protection Agency (U.S. EPA) if such information is necessary or required to administer, implement or comply with the Clean Water Act, the Safe Drinking Water Act, CERCLA or provisions and regulations relating to those acts. [See A.R.S. § 49-205(C)(2).]

A.R.S. § 49-288 (B):

This statute provides that information provided to the director which is claimed to be confidential pursuant to A.R.S. § 49-205 (A) can not be made available to the public pending the determination of confidentiality pursuant to A.R.S. § 49-205. When a determination is

made, written notice must be provided to the person claiming confidentiality. If the person does not file an action in superior court within 30 days of receipt of the notice, the information will be made public.

b. Aquifer Protection Permits

A.R.S. § 49-243(N):

This statute states that financial information submitted in Aquifer Protection Permit applications is confidential.

c. Water Quality Assurrance Revolving Fund

A.R.S. § 49-292.01

This statute provides that information submitted to the director in connection with the request for a qualified business settlement and marked "confidential" shall be kept confidential by ADEQ. See A.R.S. §49-292.01 (B) If the settlement request is denied, and the denial is appealed to the Office of Administrative Hearings, any documents submitted to the OAH as part of the appeal are not confidential. [A.R.S. 49-292.01(B)]

d. Air Quality Control

A.R.S. § 49-432(C)(1):

This statute states that ADEQ will make available to the public all records, reports of information obtained from any person unless ADEQ receives notice from the person accompanying the information that the information, if made public, would divulge trade secrets or is likely to cause substantial harm to the person's competitive position.A.A.C. R18-2-305 sets forth the administrative procedure for invoking a claim of confidentiality under A.R.S. § 49-432(C)(1).

A.R.S. § 49-432(C)(2):

This statute permits the attorney general to designate certain documents related to criminal investigations or civil actions as confidential if the disclosure would be detrimental to an ongoing criminal investigation or to an ongoing or contemplated civil enforcement action in Superior Court.

If ADEQ disagrees with the confidentiality notice, it may request the Attorney General seek a court order authorizing disclosure. See A.R.S. § 49-432(D).

Notwithstanding the confidentiality provisions of A.R.S. § 49-432(C), ADEQ must make available to the public the following information:

1. The name and address of any permit applicant or permittee.

2. The chemical constituents, concentrations and amounts of any emission of any contaminant.

3. The existence or level of a concentration of an air pollutant in the environment.

A.R.S. § 49-432(F):

This statute provides that notwithstanding the confidentiality provisions of A.R.S. § 49-432(C), the director may disclose any records, reports or information obtained from any person under the Air Quality Control chapter, including records, reports or information obtained by the director or ADEQ employees to other state employees concerned with the administration of the Air Quality Control chapter or if the records, reports or information are relevant to any administrative or judicial proceeding under the Air Quality Control chapter. The director or ADEQ employees also may disclose such information to employees of the United States Environmental Protection Agency if such information is necessary to administer and implement or comply with federal statutes or regulations. [A.R.S. § 49-433.F.]

e. Hazardous Waste

A.R.S. § 49-928(A)(1):

This statute permits the director to designate trade secrets or other information likely to cause substantial harm to the person's competitive position as confidential, when obtained by ADEQ pursuant to provisions in the Hazardous Waste Disposal chapter.

A.R.S. § 49-928(A)(2):

This statute is similar to A.R.S. § 49-205(A)(2) in that it requires the involvement of the attorney general. Public records related to an ongoing criminal action or an ongoing or contemplated civil enforcement action taken by the Hazardous Waste Compliance Unit may be withheld if the attorney general determines that disclosure would be detrimental.

A.R.S. § 49-928(B)

This statute establishes a process by which the director may disclose information which has been provided to ADEQ under a claim of confidentiality. Basically, the director may seek a court order authorizing the disclosure of confidential information. The person who submitted the information has the right to notice that a court order authorizing disclosure is being sought and has the right to a hearing on whether a court order should be issued.

A.R.S. § 49-928(D)

This statute authorizes disclosure of confidential information to other state employees concerned with administering the Hazardous Waste Disposal chapter or disclosure is authorized if the information is relevant to a judicial or administrative proceeding brought

under Chapter 5. The statute also authorizes disclosure of confidential information to employees of the United States Environmental Protection Agency if the information is necessary to administer, implement or comply with federal statutes or regulations.

For the Hazardous Waste Program, A.C.C. R-18-8-260 (D)(2)(c) sets forth the Hazardous Waste administrative process for claiming confidentiality for particular records and describes several categories of documents deemed confidential under the Hazardous Waste Management Act.

f. Pollution Prevention

A.R.S. § 49-967

This statute states that information submitted to ADEQ under the Pollution Prevention article shall be available to the public. Information may be considered confidential if the information would divulge trade secrets or cause substantial harm to the competitive position of the person who submitted the information. Also, information may be considered confidential if disclosure would be detrimental to an ongoing criminal investigation or to an ongoing or contemplated civil enforcement action brought under the Hazardous Waste Disposal chapter in Superior Court.

The pollution prevention statute is similar to A.R.S. § 49-928. It provides the same procedures for the director's disclosure of information submitted under a claim of confidentiality by seeking a court order authorizing disclosure. The statute also authorizes disclosure of information to other state employees concerned with administering the Hazardous Waste Disposal chapter and to employees of the United States Environmental Protection Agency if the information is necessary to administer, implement or comply with federal statutes or regulations.

g. Underground Storage Tanks

A.R.S. § 49-1012:

This statute provides that trade secrets and financial information related to underground storage tanks are confidential. Confidential information may be disclosed to a duly authorized congressional committee or to employees of the United States Environmental Protection Agency provided that the information is treated as prescribed in federal regulations at 40 CFR, Part 2.

2. Confidential Investigative Records

As discussed above, several statutes provide confidentiality for records in an ongoing ADEQ criminal or civil investigations. Under appropriate circumstances, ADEQ may withhold these records. Records that may be protected under this privilege include records that reveal:

a. Identities of confidential sources, including telephonic information sheets, correspondence, any document with the informant's name on it or interviews or information gathered from interviews of informants. Disclosure of such information can compromise an investigation and chill future volunteered information from the public.

b. The fact of an investigation in progress.

c. Grand Jury Material including transcripts of grand jury testimony, subpoenaed documents and matters regarding a grand jury (i.e., grand jury witness transcripts, materials obtained by grand jury subpoena or interview reports compelled by grand jury subpoena).

d. Information which constitutes an invasion of personal privacy.

e. Information about investigative techniques or procedures.

f. Information endangering the life or physical safety of law enforcement personnel.

g. Investigative reports, including investigative reports from law enforcement agencies.

h. Information that interferes with enforcement proceedings.

i. Information depriving a person of the right to a fair trial or hearing.

j. Information about an intimidation of a witness or informant.

k. Information that would allow the potentially responsible to hide or destroy evidence.

l. Information that would allow the potentially responsible to construct defenses.

m. Information that could harm future enforcement efforts.

3. Informant's Privilege.

The use of informants in environmental investigations is frequently essential to making initial discoveries of violations, and the typical informant will make it a condition of cooperation that his or her identity remain confidential. The identity of an informant who supplies information to the agency, which then conducts its own investigation, leading to the discovery of an environmental violation, need not bedisclosed. State v. Superior Court, 114 Ariz. 610, 562 P.2d 1108 (1977).

To protect an informant's identity ADEQ may withhold from the public file the identities of

confidential sources, which include telephonic contact sheets, correspondence, any document with the informant's name, employer or address on it, interviews or information gathered from interviews of informants. References to the informant's identity in any internal ADEQ memoranda or reports shall be confidential.

4. Evidentiary privileges.

a. Executive privilege.

ADEQ has the limited discretion to refuse to disclose public records on grounds of executive privilege. Executive privilege can be invoked to prevent the disclosure of public records where confidentiality is necessary to the discharge of highly important executive responsibilities involved in maintaining government operations. Public records that reflect the frank expression necessary in intra-agency advisory and deliberative communications may be kept confidential on grounds of executive privilege. The purpose underlying the doctrine of executive privilege is to encourage the free flow of advice and discussion regarding policy alternatives so that a department decision-maker may be assured that there will be no hesitation by lower level staff in providing analysis and advice in the decision-making process.

A significant limitation on the availability of executive privilege is that the public record for which the privilege is claimed must be reviewed by the director or his duly authorized representative before the privilege is available.

The scope of executive privilege includes internal policy memoranda generated by department staff for use by the director in determining department policy or administrative hearings.

U.S. v. Morgan, 313 U.S. 409 (1941); Soucie v. David, 448 F.2d 1067 (D.C. Cir. 1971); Grimm v. Arizona Board of Pardons and Paroles, 115 Ariz. 260, 564 P.2d 1227 (1977).

b. Attorney-client privilege.

The attorney-client privilege is recognized under Arizona Public Records law. Any document which is sent by ADEQ to the Office of the Attorney General requesting legal advice or comment may be withheld by ADEQ from inspection. Any document in which legal advice or legal comment is provided by the Attorney General's Office to ADEQ also may be withheld. The privilege applies to notes of meetings where an assistant attorney general is present and legal advice is given.

In addition, any document containing legal advice or comment given by the administrative counsel to the director, deputy director, division director, deputy assistant directors, or regional office managers may be withheld. The privilege applies to notes of meetings where the administrative counsel meets with any of the above managers and legal advice is given. The privilege also extends to notes of meetings between administrative counsel and ADEQ employees, where the ADEQ employee has been directed by any member of the management team to seek legal advice. Samaritan Foundation v Superior Court 173 Ariz. 427, 434, 844 P.3d 593 (1993).

5. Public records that may be an invasion of privacy.

   a. Public records in the custody of ADEQ may be withheld on the grounds that disclosure would constitute an unwarranted invasion of privacy. The test to guide this determination is twofold: (OAC may be consulted to assist in determining whether this test can be met.)

      i. The disclosure of the information constitutes an unwarranted invasion of privacy if the information disclosed is a kind that would be highly offensive to the reasonable person; and

      ii. The information is not of legitimate concern to the public.

      iii. OAC may be consulted to assist in determining whether this test can be met.

   b. Personnel files are protected.

   c. The handwritten personal notes or diaries of employees may also be protected if these notes or diaries did not have to be maintained as a requirement of their employment and are not prepared during their work hours.

6. Disclosure of public records that would not be in the best interest of the state.ADEQ has discretion to refuse to disclose public records on the ground that disclosure is not in the best interest of the state. This is available if disclosure would result in substantial and irreparable public harm. ADEQ may refuse to disclose on this ground only when the effectiveness of the agency will be seriously impaired in the performance of its duties if disclosure of the information is made.

7. A record which has been sealed by court order.

The court order which identifies the records that have been sealed will be attached to those records.

C. Preliminary Drafts

Generally, preliminary drafts of contracts or reports are not considered public records and, therefore, need not be disclosed. (See OP. Atty. Gen. No. 70-1.)

GUIDELINES FOR USE OF CONFIDENTIALITY REQUEST FORM

ADEQ personnel, receiving documents from outside the agency, in the course of agency business, should use the following guidelines in determining whether to request the supplier of the document(s) to complete a Confidentiality Request Form (CRF):

1. A CRF should always be completed when it appears that the document(s) may fall within the provisions of the following statutes:

   a. A.R.S. § 49-205(A)(1)

   b. A.R.S. § 49-243(N)

   c. A.R.S. § 49-432(C)(1)

   d. A.R.S. § 49-928(A)(1)

   e. A.R.S. § 49-967(A)(1)

   f. A.R.S. § 49-1012(A)

2. A CRF should always be completed in any case where it appears from the nature of the document(s) that it may contain "trade secrets".

3. A CRF should always be completed in any case where it appears from the nature of the document(s) that it may contain sensitive or confidential information.

4. A CRF should always be completed in any case where it appears from the nature of the document(s) that it may contain financial information.

5. A CRF should always be completed in any case where the document(s) are marked confidential or confidentiality is actually claimed.

IF THERE ARE ANY QUESTIONS REGARDING THE USE OF THE CRF, CONTACT THE OFFICE OF ADMINISTRATIVE COUNSEL (OAC).

APPROVED BY

For Historical Policy Document, see Policy #0032.000. (Place cursor on the inverted triangle and press enter to see this document.)

CONFIDENTIALITY REQUEST FORM

YOU ARE HEREBY NOTIFIED THAT YOU MAY ASSERT A CLAIM OF CONFIDENTIALITY REGARDING THE DOCUMENT(S) YOU ARE SUPPLYING TO THE ARIZONA DEPARTMENT OF ENVIRONMENTAL QUALITY (ADEQ). IN ORDER TO CLAIM CONFIDENTIALITY YOU MUST COMPLETE SECTIONS I, II AND III OF THIS FORM. IF YOU DO CLAIM CONFIDENTIALITY, ADEQ WILL MAKE A DETERMINATION ON YOUR CLAIM AND ADVISE YOU IN WRITING WITHIN TEN (10) WORKING DAYS. IF YOU DO NOT CLAIM CONFIDENTIALITY, THESE DOCUMENTS WILL BE CONSIDERED PUBLIC RECORDS AND BE IMMEDIATELY AVAILABLE TO THE PUBLIC.

I. I do ( ) do not ( ) claim confidentiality for these records.

If you checked "do" please complete sections II and III below.

II. Please state whether confidentiality is claimed for all or part of the document(s). If for part only, specify those parts for which confidentiality is claimed.

III. Please state reason for claim of confidentiality.
( ) Document(s) contains "Trade Secrets".

Explanation:

APPENDIX F

0042.000 **INFORMATION TECHNOLOGY STANDARDS DEVELOPMENT**

Level One **Arizona Department of Environmental Quality**

Originator: Karen J. Heidel, Deputy Director

Contact for Information : Linda Cannoli

Issue Date: May 26, 1995

PURPOSE

The purpose of this policy is to establish a department-wide process for developing or modifying information technology standards in a timely manner to meet program needs while limiting the scope of standards to those necessary to meet department-wide goals and needs for cross-agency communication. This process will include procedures for recommending software and hardware standards, for requesting purchases of non-standard software and hardware and for reviewing policies pertaining to data and information technology prior to their submittal to the Policy Review Committee.

POLICY

ADEQ will maintain standards to facilitate connectivity, cost-effectiveness, data sharing, compatibility, and infrastructure support for information technology.

A committee (Information Technology Standards Committee) is formed to develop procedures to propose and recommend information technology standards.

The Information Technology Standards Committee will develop a procedure to identify outstanding Information Technology standard issues.

Procedures will be developed and kept in other documents.

RESPONSIBILITY

All employees are responsible for complying with the policy.

Level One
Arizona Department of Environmental Quality

APPROVED BY

APPENDIX G

0001.000 POLICY DEVELOPMENT AND IMPLEMENTATION

Level One **Arizona Department of Environmental Quality**

Originator: Karen J. Heidel
Deputy Director

Contact for Information: Susan Bentley-Johnston
Program Support & Assistance

Issue Date: April 5, 1996

PURPOSE
The purpose of this policy is to formalize the method for policy development and adoption within ADEQ.

DEFINITIONS
Policy is a written instruction, whether formalized or not, which interprets the authority, responsibility or activities for ADEQ.

Internal Policy is a written or oral instruction, whether formalized or not, which impacts the internal operation of ADEQ or one of its divisions, sections, or units or interprets the authority, responsibility or activities of ADEQ staff.

Procedures are processes that direct the way policies are implemented, but do not change the content of the policies.

Substantive Policy Statement is a term defined by Arizona statute. A.R.S. § 41-1001 (20) says:

> 'Substantive policy statement' means a written expression which informs the general public of an agency's current approach to, or opinion of, the requirements of the federal or state constitution, federal or state statute, administrative rule or regulation, or the final judgement of a court of competent jurisdiction, including where appropriate, the agency's current practice, procedure, or method of action based upon that approach or opinion. A substantive policy statement is advisory only. A substantive policy statement does not include internal procedural documents which only affect the internal procedures of the agency and does not impose additional requirements or penalties on regulated parties, confidential information or rules adopted in accordance with this chapter.

POLICY

It is the policy of ADEQ to have administrative review of all proposed policies or policy changes using the Policy Management System. Adopted policies, both internal and external, or policy revisions will be placed into the Folio Database. Only those documents which have successfully completed the Policy Management System review process will be considered promulgated ADEQ policies.

RESPONSIBILITY

Unit and section managers are responsible to ensure that (1) all department documents containing policy statements (2) or oral instructions that constitute policy have a concomitant formal policy developed through the Policy Management System. The Policy Review Committee (PRC) and the Management Team will continue to review policies as required under the Policy Management System.

Any ADEQ employee may develop a draft policy through this system and submit it for review by the Policy Review Committee.

Program Support and Assistance is responsible for the management and administration of the Policy Management System.

PROCEDURES

Procedures for policy development and review are located in Folio under Manager's Guide option (See Manager's Guide Table of Contents, Item C.)

APPROVED BY

APPENDIX H

0154.000 **ADDRESSING SPIKE AND SURROGATE RECOVERY AS THEY RELATE TO MATRIX EFFECTS IN WATER, AIR, SLUDGE AND SOIL MATRICES POLICY**

Level One **Arizona Department of Environmental Quality**

Originator: Kenyon C. Carlson, Manager
Quality Assurance/Quality Control (QA\QC) Unit

Contact For Information Kenyon C. Carlson, Manager
Quality Assurance/Quality Control (QA\QC) Unit

Issue Date: October 23, 1998

PURPOSE

The Arizona Department of Health Services (ADHS) has not established a comprehensive policy on the issue of matrix spike or surrogate recoveries because they do not have the authority to establish criteria by which ADEQ will either accept or reject data.

This policy will assure that all data submitted to ADEQ meets regulatory requirements and are legally defensible by establishing alternative criteria for when the established method recovery acceptance criteria for matrix spikes and/or surrogates are exceeded.

ADEQ is concerned with the assumption that if spike and/or surrogate recoveries exceed method acceptance criteria and that if those results can be duplicated without re-extracting the sample, the failure of that quality control criteria is a result of matrix effects. Duplication of out-of-range results can be the result of influences other than matrix effects and could be indicative of the method or instrument being out-of-control.

The ADEQ QA/QC Unit believes a more accurate and reliable assessment of possible matrix effects can be established using either a (1) dilution technique, (2) the method of standard additions, or (3) analyzing a laboratory fortified blank (LFB) or a laboratory control sample (LCS). Because ADEQ is a regulatory agency, compliance results must be able to meet all legal constraints and uphold all analytical method requirements.

AUTHORITY

A.A.C. R18-4-106 and R9-14-608.

DEFINITIONS

Data: For the purposes of this policy, data is defined as ‘ raw data’ (examples include but are not limited to calibration curves, chromatograms, spectras, sample preparation and injection logs etc.) and does not include laboratory reports. (Contact the QA unit for further information.)

Laboratory Fortified Blank (LFB): (aka blank spike)An aliquot of organic free reagent water to which known quantities of the method analytes are added in the laboratory. The LFB is analyzed exactly like a sample, and its purpose is to determine whether the methodology (analytical process) is in control, and whether the laboratory is capable of making accurate and precise measurements at the required method detection limit.

Laboratory Fortified Blank Duplicate (LFBD): (aka blank spike duplicate) A duplicate sample of the aliquot of reagent water to which known quantities of the method analytes are added in the laboratory. The LFBD is analyzed exactly like a sample, and its purpose is to determine whether the methodology (analytical process) is in control, and whether the laboratory is capable of making accurate and precise measurements at the required method detection limit.

Laboratory Control Sample (LCS): A sample of clean dirt or sand to which known quantities of the method analytes are added in the laboratory. The LCS is extracted and analyzed exactly like a sample, and its purpose is to determine whether the methodology (sample preparation and analytical process) is in control, and whether the laboratory is capable of making accurate and precise measurements at the required method detection limit.

Laboratory Control Sample Duplicate (LCSD): A duplicate sample of clean dirt or sand to which known quantities of the method analytes are added in the laboratory. The LCSD is extracted and analyzed exactly like a sample, and its purpose is to determine whether the methodology (sample preparation and analytical process) is in control, and whether the laboratory is capable of making accurate and precise measurements at the required method detection limit.

Laboratory Fortified Sample Matrix (LFM): (aka matrix spike) An aliquot of an environmental sample to which known quantities of the method analytes are added in the laboratory. The LFM is analyzed exactly like a sample, and its purpose is to determine whether the sample matrix contributes bias to the analytical results and therefore determines to what degree the method is successful in analyzing the target analytes. The background concentrations of the analytes in the sample matrix must be determined in a separate aliquot and the measured values in the LFM corrected for background concentrations.

Laboratory Fortified Sample Matrix Duplicate (LFMD): (aka matrix spike duplicate) A duplicate sample of the aliquot of an environmental sample to which known quantities of the method analytes are added in the laboratory. The LFMD is analyzed exactly like a sample, and its purpose is to determine whether the sample matrix contributes bias to the analytical results and therefore determines to what degree the method is successful in analyzing the target analytes. The background concentrations of the analytes in the sample matrix must be determined in a separate aliquot and the measured values in the LFMD corrected for background concentrations.

Matrix: The predominant material, component or substrate which contains the analyte of interest. Matrix is not necessarily synonymous with phase (liquid or solid).

Matrix Interference: Also referred to as matrix effects. Matrix spike interference are those chemical and/or physical interferences that impede the analytical instrumentation in detecting the true value concentration of a target analyte within a sample. One possible source of matrix interferences may be caused by contaminants that are co-extracted from the sample and result in a positive or negative bias. The extent of matrix interferences will vary considerably from source to source, depending upon the nature and diversity of the sample matrix.

Method of Standard Additions: A technique used most commonly in metals analysis by atomic absorption; however, it can be applied in many areas of the laboratory. It serves to correct for matrix effects in the sample. Aliquots of a sample are spiked with at least three different concentrations of a standard.

Surrogate: A pure analyte, which is extremely unlikely to be found in any sample, and which is added to a sample aliquot in known amounts before extraction and is measured with the same procedures used to measure other sample components. A surrogate behaves similarly to the target analyte and its use is most often used with organic analytical procedures. The purpose of a surrogate analyte is to monitor method performance with each sample.

POLICY

ADEQ will not accept test results for regulatory purposes when the LFM and/or surrogate recovery exceed the acceptance criteria unless the laboratory has demonstrated that the sample itself is responsible for the QC results exceeding the methods acceptance criteria.

RESPONSIBILITY

The ***ADEQ Program staff*** will be responsible for reviewing the final report or the quality control summary sheets which accompany the final results of the laboratory analysis to verify that matrix spikes and/or surrogate recoveries were within the acceptance criteria. If the program staff are uncertain as to how to evaluate the final report, or if required information is missing, it shall be the responsibility of the program staff to forward the information to the ADEQ QA/QC Unit for review and recommendations.

The ***ADEQ QA/QC Unit*** will review data referred by program staff to ensure that the procedures outlined in Attachment A of this policy were followed by the laboratory and to report their findings to the appropriate ADEQ program staff.

APPLICABILITY

This policy is applicable to all types of water, air, sludge, and soil matrices regardless of the method of analysis.

PROCEDURES

The ***ADEQ program staff*** shall review the final report or the quality control (QC) summary sheet which accompanies the final report. ADEQ program staff shall assess the results of the LFM and LFMB on the QC Summary sheet to determine if the recoveries are within the acceptance range. If the LFM or LFMB results exceed the established recovery criteria, ADEQ program staff will assess the recovery criteria for those out of range analytes in either the LFB/LFBD or LCS/LCSD. If the required information is not included with the final report or program staff are uncertain as how to evaluate the final report, they shall notify the QA/QC Unit so the QA/QC staff can perform a more thorough evaluation of the results.

The ***ADEQ QA/QC staff***, if necessary, shall request a laboratory data package to review the raw data, determine the validity of the results and compliance with the ADEQ data reporting policy. The QA/QC Unit shall also submit in writing, to the program staff, the data validation findings and the ADEQ QA/QC Unit's recommendations.

ATTACHMENT A

LABORATORY PROCEDURES

The ADEQ policy for addressing spike and surrogate recovery as they relate to matrix effects in water, air, sludge and soil matrices suggests three different techniques (analysis of an LFB/LFBD or LCS/LCSD pair, dilution procedure, or the standard additions technique) which may adequately explain the out-of-range QC results of samples. These three techniques do not represent an all inclusive list for demonstrating matrix effects within a sample and laboratories may have alternate and valid techniques to demonstrate matrix interference. These alternate techniques should be discussed with and approved by the ADEQ QA Unit prior to analysis to avoid the rejection of data.

ADEQ also requires the analyses of either an LFB/LFBD, LCS/LCSD or LFM/LFMD pair to satisfy the precision requirements for drinking water methods. More useful information can be obtained regarding precision when comparing samples containing target analytes. Very little useful precision information is obtained when comparing the instrument precision using two samples that are non detect. Whenever included in the analytical batch, the laboratory must report the results of the LFB/LFBD or LCS/LCSD in addition to the LFM/LFMD to ADEQ and shall include the numerical values established by the laboratory for the QC acceptance criteria whenever the method has not provided any.

While the method would require a re-extraction of that sample, to confirm matrix interference, if the LFM and/or the LFMB fall outside the method's acceptance criteria, ADEQ will accept the results of the LFB/LFBD or LCS/LCSD which demonstrate that the analytical process is in control. The LFB/LFBD and LCS/LCSD provide an interference free matrix such that if the surrogates and/or matrix spike analytes are within the method's acceptance criteria, then there is compelling data that an instrument is operating properly, the extraction procedure provided no bias, and the method is in control. The LFB/LFBD must be analyzed with the same batch as the LFM/LFMD for ADEQ to accept the LFB/LFBD results. The LCS/LCSD samples must be extracted and analyzed with the same batch as the LFM/LFMD samples for ADEQ to accept the results of the LCS/LCSD samples. The laboratory shall include the numerical values established by the laboratory for the QC acceptance criteria whenever the method has not provided any.

Another option is the dilution technique. The dilution technique is particularly well suited for demonstrating matrix effects in the LFM samples for analyses that don't require extraction procedures. Laboratories performing analytical work for ADEQ that suspect matrix interference in LFM samples may dilute that sample such that all suspected matrix effects are diluted out as well prior to spiking. Once the matrix effects have been diluted out, recovery of the matrix spikes and surrogates should fall within the acceptable recovery criteria established by the method, or the lab if none are given in the method. The dilution of samples suspected of having matrix interference such that interference is no longer a factor strongly suggests that there may have been matrix effects in the sample and the recovery of the spiked analytes within the acceptance range demonstrates the instrumentation and method are in control. ADEQ will accept use of the dilution technique to demonstrate matrix effects in LFM and LFMD samples because not every sample is matrix spiked and it cannot be assumed that the matrix effects observed in one sample are representative of the entire

sample batch.

Because the dilution technique raises the reporting level of an analyte, it may not be a suitable technique to demonstrate matrix interference if the resulting reporting level exceeds the regulatory (trigger) or action level. The method of standard additions would be a preferred technique to help correct for positive or negative bias in the samples because this technique is unlikely to raise the reporting level of regulated contaminants that may be present in the sample. The method of standard additions usually employs aliquots of a digested or extracted sample which are spiked with at least three different concentrations of a standard. The standard additions are chosen to bracket the unknown sample concentration and the response of the instrument must be linear.

Those samples whose matrix spikes or surrogate recoveries continue to fall outside the acceptance criteria after any of the above three techniques, or an alternate method pre-approved by the ADEQ QA Unit have been employed, shall be reviewed by ADEQ on a case-by-case basis. Any results reported which are affected by matrix interference shall be flagged as an estimated quantitation.

APPENDIX I

0155.000 **ANALYTICAL METHODS HAVING PROVISIONS FOR A ONE-POINT CALIBRATION AND CONTINUING CALIBRATION VERIFICATION CONSTRAINTS POLICY**

Level One **Arizona Department of Environmental Quality**

Originator: Kenyon C. Carlson, Manager
Quality Assurance\Quality Control(QA\QC) Unit

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Issue Date: October 23, 1998

PURPOSE

Most analytical methods have established upper and lower control limits for CCV's and when the recovery exceeds those limits the method is considered "out-of-control". ADEQ is concerned with the assumption that the 'data are not impacted', as reported by laboratories when the upper control limit of a CCV has been exceeded in a non-detect result. Currently, there is no way to differentiate between an instrument that has gained sensitivity and one that has drifted out of control when the upper control limit of a CCV is ignored.

Adherence to this policy will assure that all laboratory-generated data submitted to ADEQ meets regulatory requirements and are legally defensible.

Because ADEQ is a regulatory agency, compliance results must be able to meet all legal requirements. Where CCV requirements are part of the test method and where test methods are part of the regulatory requirements, then the CCV requirements as dictated by the analytical method must be followed.

AUTHORITY

A.A.C. R18-4-106 and R9-14-608.

The EPA methods continue to be written such that upper and lower control limits for the CCV are established and there is no documentation which permits one to ignore the violation of an upper control limit in light of certain conditions.

DEFINITIONS

Continuing Calibration Verification Standard (CCV)--Consists of an aliquot of reagent water to which known quantities of the method analytes are added by the laboratory. The CCV' s purpose is to determine whether the methodology is ' in control' by verifying the linearity of the calibration curve and to assure that the sample results reflect accurate and precise measurements.

Data--For the purposes of this policy, data is defined as raw data (examples include but are not limited to calibration curves, chromatograms, spectras, injection logs, etc.) and does not include laboratory reports. (Contact the QA unit for further information).

POLICY

From a regulator's perspective, a laboratory must follow the method as written to ensure the analytical data generated is defensible and can survive the scrutiny of litigation. ADEQ will not accept test results for regulatory purposes when the CCV's acceptance criteria have been exceeded. This includes sample results where the upper control limit of the CCV has been exceeded and the result is reported as non-detect.

However, in the event a CCV exceeds its control limits for a detect sample, ADEQ allows the laboratory to either 1)recalibrate the entire multi-point curve and reanalyze the samples or 2) perform a one-point calibration as the method permits.

RESPONSIBILITY

The ADEQ QA/QC staff will be responsible, when reviewing data for the purpose of recommending to ADEQ program staff to either accept or reject such data, to ensure that the procedures outlined in this policy are followed.

APPLICABILITY

This policy is only applicable to those methods which provide for a one-point calibration and those water matrices for the analysis of volatile organic compounds (VOCs), synthetic organic compounds (SOCs), and inorganic compounds (IOCs) analyzed using 40 CFR methods (ex. 200, 500, and 600 series). This policy does not apply to those samples analyzed using SW-846 methods.

LABORATORY PROCEDURES

EPA and the ADEQ QA/QC Unit require that laboratories which elect to recalibrate using a one-point calibration must demonstrate there is adequate instrument sensitivity to detect a peak at the method reporting level for those contaminants. Therefore, to justify reporting sample results as non-detect when the control limits of a CCV have been exceeded, the laboratory must recalibrate using a standard at the method reporting level and re-run all the samples or extracts after that CCV.

The laboratory must detect a significant peak for each analyte reported in the method reporting level standard. A significant peak is considered to be one in which the peak is at least 3 to 5 times the signal to noise ratio (40 CFR, Part 136, Appendix B, Procedure section 1a).

This ADEQ policy provides a means for laboratories to demonstrate that sample results are, in fact, non-detect for target analytes. The method reporting level standard must be analyzed (and determined to be acceptable) before reanalyzing any samples in a run.

Non-detects:

To report a non-detect result using a one-point calibration, the laboratory must meet the following requirement: Establish the absence of a significant peak at the retention time of the target analyte. The absence of a significant peak at the retention time of the target analyte is defined as one whose response is less than that of the analyte present in the low level standard (which must be prepared at the reporting limit) used for the one-point calibration.

Detects:

To report a detect result using a one-point calibration, a laboratory must meet the following requirement: a one-point calibration must be performed so that the concentration of the one-point calibration standard is within ±20% of the concentration of analyte detected in a sample.

ATTACHMENT

STATEMENT OF POSITION

There has been some debate among the laboratory community concerning continuing calibration verification (CCV's) standards and non detect samples. Most analytical methods have established upper and lower control limits for CCV's and when the recovery exceeds those limits the method is considered "out of control". Recently, there has been a growing consensus among some laboratories that an analytical method is ***not*** out of control if the upper control limit of the CCV is exceeded providing the sample is a non-detect. The reasoning here is that the instrument has somehow "gained" sensitivity and if there were anything in the sample, it would surely have been detected.

The ADEQ QA/QC Unit understands this logic and recognizes that it may true in some cases. However, this is only one of several possibilities. Another possibility is that the analytical method is now out of control. ADEQ is concerned with the assumption that the 'data are not impacted',as reported by laboratories when the upper control limit of a CCV has been exceeded in a non-detect result. Currently, there is no way to differentiate between an instrument that has gained sensitivity and one that has drifted out of control when the upper control limit of a CCV is ignored.

As a regulatory agency, ADEQ cannot assume that each time the upper control limit is exceeded, it is the result of increased instrument sensitivity. Such an assumption can result in the court or the hearing officer invalidating or dismissing the analytical results because an integral portion of the method's quality control has been omitted. The ADEQ Quality Assurance\Quality Control Unit has discussed this subject at length with EPA Region IX's Quality Assurance Management Section. Region IX concurs with the ADEQ's QA\QC Unit's interpretation. They have further expressed their concern that ignoring established upper control limits for the CCV is not in line with "good laboratory science" and may invite abuse and even laboratory fraud.

APPENDIX J

0034.001 LOCATIONAL DATA POLICY

Level One Arizona Department of Environmental Quality

Originator: GPS Subcommittee

Contact For Information: Patti Tuve

Issue Date: February 3, 1995 **Amended:** November 13, 1996

PURPOSE

The Locational Data Policy (LDP) establishes standards and makes recommendations for collecting and documenting all locational coordinates thereby allowing integration of the data based upon location, promoting its use for cross-media environmental analyses and management decisions.

POLICY

Latitude and longitude coordinates shall be collected for and documented with environmental and other related data for all activities that define a location. Documentation is required for latitude and longitude accuracy, description and method as prescribed in the accompanying procedures.

The Global Positioning System is the preferred method for the most accurate latitude and longitude possible, but other methods such as map interpolation, cadastral surveying, photo interpretation and address matching are not precluded.

All new locational data must have an accuracy of twenty-five (25) meters or better, and this policy does not rescind or preclude other program-specific policy and guidance that contain this requirement.

RESPONSIBILITY

It will be the responsibility of all ADEQ managers to ensure that information collection and reporting systems under their direction are in compliance with this policy. Managers of individual data collection efforts will be responsible to determine the exact levels of precision and accuracy necessary to support their mission within the context of this goal.

Such documentation will permit other users to evaluate whether those coordinates can support secondary uses, thus addressing ADEQ's data sharing and integration objectives. To that end, recommended labeling for data fields is as follows:

"Latitude"
"Longitude"
"Method"
"Accuracy"
"Description"

PROCEDURES

1. Coordinates: Latitude and longitude coordinates and data shall be collected and documented as follows in accordance with Federal Interagency Coordinating Committee for Digital Cartography (FICCDC) recommendations.

   The coordinates may be present individually or multiple times, to define a point, line, or area, according to the most appropriate data type for the entity being represented. The format for representing this information is:

+/- DDMMSS.SSSS	latitude
+/- DDDMMSS.SSSS	longitude

   where:

   - # Latitude is always presented before longitude.
   - # DD represents degrees of latitude; a two-digit decimal number ranging from 00 through 90.
   - # DDD represents degrees of longitude; a three-digit decimal number ranging from 000 through 180.
   - # MM represents minutes of latitude or longitude; a two-digit decimal number ranging from 00 through 59.
   - # SS.SSSS represents seconds of latitude and longitude, with a format allowing possible precision of ten-thousandths of a second.
   - # + specifies latitude north of the equator and longitudes east of the prime meridian.
   - # - specifies latitudes south of the equator and longitudes west of the prime meridian.

2. Method: The specific method used to determine the latitude/longitude coordinates (e.g. GPS, photointerpretation, address matching, cadastral survey, map interpolation, etc.).

3. Accuracy: The estimate of accuracy for the method used to determine the latitude/longitude

coordinates will be specific to each method. Accuracies used will be as follows:

Differential GPS	2 - 5 meters
Photo Interpretation	1 - 40 meters
Address Matching	50 - 100 meters
Cadastral Survey	25 - 100 meters
Map Interpolation (dependent on map scale)	25 - 100 meters

Conventional surveying accuracy is dependent on survey method, and should be expressed in terms of the most precise units of measurement used (e.g., if the coordinates are given to tenth-of- seconds precision, the accuracy estimate should be expressed in terms of the range of tenth-of-seconds within which the true value should fall, such as +/- 0.5 seconds.) One second is equal to 30.8 meters latitude, and approximately 25.9 meters longitude, which has some variations across the state.

4 .Description: Textual description of the entity to which the latitude/longitude coordinates refer (e.g., north-east corner of a site, entrance to facility, point of discharge, drainage ditch, etc.).

APPROVED BY

FOR HISTORICAL DOCUMENT, SEE 0034.000.